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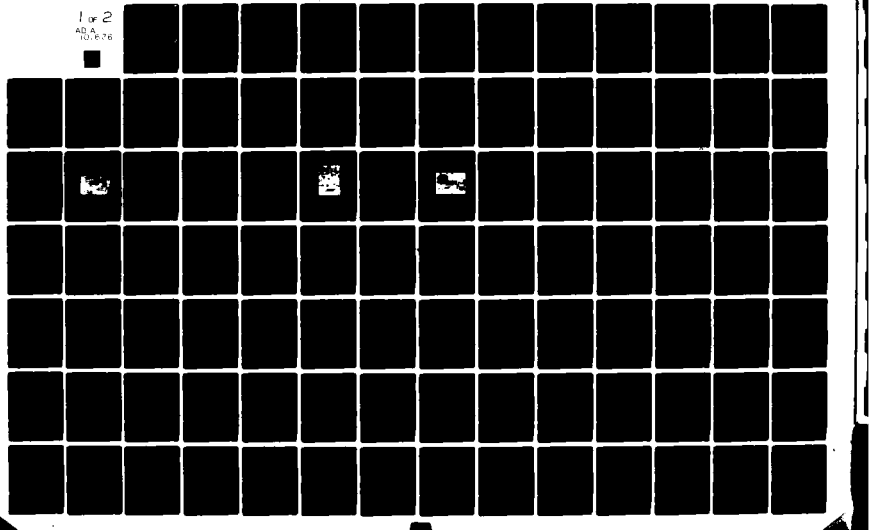

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## ABSTRACT

The Evaluation of a Valveless Disposable Respirator For Use As Respiratory Protection Against Exposure to Halothane (2-Bromo-2-Chloro-1,1,1-Trifluoroethane). (December 1980)

Glenn Lawrence Gaudet, B.S., Tulane University

Chairman of Advisory Committee: Dr. R. J. Vernon

Health professionals are concerned about the health hazards associated with exposure to waste anesthetic gases and vapors. The concern has grown since some epidemiological, human, and animal studies have suggested that such exposure results in a variety of anomalies among operating room personnel.

The concentration of waste anesthetic gases and vapors in the operating room has greatly decreased through the use of scavenging equipment. However, it is unlikely that a zero waste anesthetic agent concentration will be attained through this method. Since the existance of a truly "safe" exposure level has not been conclusively proven, it is desirable to provide the operating room personnel with additional protection, i.e., personal protective equipment, to reduce exposure to halogenated anesthetic agents.

Activated charcoal has been shown to adsorb halogenated anesthetic agents. However, organic vapor respirators are normally bulky and would not be accepted for use by a surgeon or other operating room personnel. The Minnesota Mining and Manufacturing Company (3M) has marketed a disposable respirator called the 3M Spray Paint Respirator #8711. The

respirator has the external configuration of a surgical mask. Since this respirator contains activated charcoal and may be accepted by operating room personnel, it was tested against a Halothane anesthetic agent challenge atmosphere.

The results of the study indicate that when the 3M #8711 respirator is challenged with a 140 parts per million (ppm) Halothane concentration for 7.25 hours, the peak concentration inside of the mask is less than 50 ppm. In addition, the time weighed average concentration inside of the mask does not exceed 50 ppm, the Threshold Limit Value. These conclusions apply when there is no water in the breathing system. To simulate the wet human respiratory system, water was to be used in the breathing machine equipment. Unfortunately, equipment failure prevented full experimentation with water. However, the experimental work performed with water is discussed in an appendix included with the thesis. The data provided in the appendix suggests that for valveless respirators, the worst performance occurs when there is no water in the system. The implication is that when the respirator is worn by a human, the protection improves because of the liquids in the body.

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A Thesis

by

GLENN LAWRENCE GAUDET

Submitted to the Graduate College of
Texas A&M University
in partial fulfillment of the requirement for the degree of

MASTER OF SCIENCE

December 1980

Major Subject: Industrial Hygiene

# THE EVALUATION OF A VALVELESS DISPOSABLE RESPIRATOR FOR USE AS RESPIRATORY PROTECTION AGAINST EXPOSURE TO HALOTHANE (2-BROMO-2-CHLORO-1,1,1-TRIFLUOROETHANE)

A Thesis

by

GLENN LAWRENCE GAUDET

Approved as to style and content by:

_____
(Chairman of Committee)

_____
(Head of Department)

_____ _____
(Member) (Member)

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# INTRODUCTION

One of the fundamental principles of industrial hygiene is that personal protective equipment devices are "last resort" types of controls to prevent accidental injuries. They are to be used as supplemental controls only where engineering controls cannot be used, or, when engineering controls are inadequate. This fundamental principle is stated in the standards adopted under the Occupational Safety and Health Act of 1970[1].

Organic vapor-removing respirators are one type of personal protective equipment. In the absence of engineering controls, their use can be life saving, as most cases of intoxication occur when the exposure is through the respiratory tract. These respirators are equipped with a container or cannister filled with a sorbent which absorbs, adsorbs, or reacts with the hazardous vapor in the atmosphere.

In general, organic vapor-removing respirators are divided into two categories - gas masks and chemical cartridge respirators. The gas mask is a full face respirator which is used when the hazardous vapors are irritating or damaging to the eyes. The sorbent cannister for heavy duty usage is large and is normally worn on a chest harness or strapped to the belt. The cannister is then connected by a hose to the face piece.

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Citations used on the following pages follow the style of the American Industrial Hygiene Association Journal.

Chemical cartridge half mask respirators cover the wearer's nose and mouth. These respirators usually carry relatively small sorbent cannisters which can be used for short periods of time in relatively low concentrations of vapor.

Both the gas mask and chemical cartridge respirators use an exhalation valve which restricts the flow of air through the sorbent bed in one direction. That is, the contaminated air initially flows into the respirator through the sorbent bed where it is purified. Then, the air is exhaled from the respirator through the exhalation valve without passing through the sorbent bed again. The advantage of using an exhalation valve in a respirator is that the breathing resistance during the wearer's exhalation breath is reduced.

The Minnesota Mining and Manufacturing Company (3M) has introduced a disposable half mask organic vapor respirator without an exhalation valve - the 3M Spray Paint Respirator #8711. Without a valve, the airflow through the activated charcoal sorbent bed can go in two directions. In other words, the inspired air flows through the sorbent bed and the expired air also passes through the sorbent bed. This feature is considered significant because the sorbent in the valveless respirator is partially regenerated by the exhaled breath. Consequently, the air purifying capability of the respirator is thought to be extended by the valveless design.

Halothane (2-Bromo-2-Chloro-1,1,1-Trifluoroethane) vapor has been chosen as the challenge agent to evaluate the 3M #8711 respirator because of the possible health hazards associated with exposure to

anesthetic agents in the hospital operating room. Of the numerous inhalation anesthetic agents available, the gas nitrous oxide and the volatile liquid Halothane are most widely used[2]. A preliminary test of the effectiveness of the 3M #8711 respirator when challenged to nitrous oxide was conducted by the author in March 1980. The test indicated that the 3M #8711 respirator will provide essentially no protection against nitrous oxide. Consequently, a decision was made to use only Halothane as the challenge agent.

It is expected that the use of the 3M #8711 respirator can keep the exposure of operating room personnel to Halothane vapors below 50 ppm, the Threshold Limit Value. The 3M #8711 respirator has the external configuration of a surgical mask. Since operating room personnel normally use surgical masks for asepsis reasons, the use of a similar mask with activated charcoal is not a significant deviation from their normal work routine.

# LITERATURE REVIEW

Title 30, Code of Federal Regulations, Part 11 (30CFR11) provides the criteria which must be met for a respirator to be given an approval by the U.S. Department of Labor's Mine Safety and Health Administration (MSHA), and the U.S. Department of Health and Human Services' National Institute for Occupational Safety and Health (NIOSH). The 30CFR11 regulation does not address the testing of valveless organic vapor respirators.

In 1975-1976, the Bendix Corporation had been contracted by the National Aeronautics and Space Administration and NIOSH to improve the respirator certification aspects of 30CFR11. Bendix was also asked to develop a certification testing program for valveless organic vapor respirators.

Using 15 different organic solvents, Bendix conducted a variety of tests to establish a recommended certification testing program for valveless respirators. As of June 1980, the Bendix report had not been adopted. There is still no criteria by which a valveless organic vapor respirator can receive MSHA-NIOSH approval. The Bendix report[3], however, produced very interesting performance data which is the basis of this thesis work.

The concentration of challenge agent inside of a respirator with an exhalation valve increases as the time of exposure to the challenge vapor increases[4]. After a certain time of exposure, the concentration of challenge agent inside the mask is essentially the same

as the concentration of agent outside of the mask. The absorption capability of the sorbent has therefore been exhausted. However, the Bendix study reported that with a valveless respirator, the challenge agent concentration inside the respirator increases initially until an equilibrium penetration value is reached. That is, the concentration of challenge vapor inside the respirator increases to a point less than the challenge concentration at which it remains constant. The Bendix study reported that the equilibrium point for the organic vapors they tested was less than 10% of the challenge vapor concentration. This means that with a challenge agent concentration of 1000 parts per million (ppm) outside of the respirator, the concentration of challenge agent inside the respirator will be no more than 100 ppm - and probably less. This performance characteristic was attributed to the valveless configuration of the respirator. The exhaled air passing through the sorbent bed was reported to remove some of the contaminant from the activated charcoal.

The Bendix study tested the respirators using a breathing machine to simulate human respiration. However, all of the inhaled air which had passed through the mask was vented to an exhaust. The exhalation breath used to breathe out of the respirator was composed of clean humidified air. In the human respiratory system, the exhalation breath would not be free of the challenge agent that had entered the respirator.[5] Therefore, the experimental equipment for this research differed from the Bendix experimental equipment in that any challenge agent which penetrated the respirator became a part of the exhalation breath. Unlike the Bendix study, the respirator was not washed out with clean air with each

breath.

Halothane vapor ($CF_3CHBrCl$) was chosen as the challenge agent for this research because of the possible health hazards associated with exposure to trace concentrations of anesthetic agents. Halothane is a volatile liquid that was synthesized in 1956 and was introduced into clinical anesthesia the same year. Halothane is non-flammable and non-explosive. The chemical is a clear, colorless liquid with a molecular weight of 197.4 and a liquid specific gravity of 1.87. The boiling point at 760 millimeters of mercury (mm Hg) is 50.2°C. The vapor pressure of Halothane at 20°C is 243 mm Hg. The solubility of Halothane in water is 0.0345 grams/milliliter at 20°C. The solubility of Halothane in blood is 0.0160 grams/milliliter at 37°C. When moisture is present, Halothane vapor attacks aluminum, brass, and lead, but not copper. The anesthetic agent is normally used by bubbling air through the volatile liquid in an anesthesia cart. The vapor is then administered to the surgical patient. The minimum anesthetic concentration is 7700 ppm, and anesthesia is maintained at 5000 to 20000 ppm.[2]

The use of inhalation anesthetic agents has greatly relieved the pain man would experience during surgical procedures. However, for many years, operating room personnel have been concerned about the effects of exposure to trace concentrations of anesthetic agents. A 1922 editorial[6] in the periodical Anaesthesia and Analgesia indicated that anesthesiologists recognized the possible deleterious effects from repeated exposure to anesthetic gases during their administration

to patients. In the editorial, an associate of a famous Chicago anesthesiologist was quoted as saying, "While we have not been able to prove it definitely, still we have much evidence to show that the administration of anesthetics, over a long period of time, produces a condition of nephritis that results fatally".

Since that 1922 editorial, and particularly within the past 25 years, many studies about the adverse health effects of waste anesthetic agents have been conducted. The epidemiologic studies conducted prior to 1975 indicate the presence of a variety of anomalies among operating room personnel, such as increased spontaneous abortions, congenital anomalies, along with an increased incidence of cancer, hepatic, and renal diseases. In addition, an increased suicide rate was noted in the studies. Since about 1976, however, there have been several articles which have questioned the previous works in this area.

In 1978, Ferstandig[7] attacked the epidemiological studies relating reproductive disease and exposure to anesthetic agents. He feels that the epidemiological studies are inconclusive because they were not designed to test the cause and effect relationship between the anesthetic agents and the worker's reproductive disease.

In 1979, the ad hoc committee of the American Society of Anesthesiologists reported[8] an epidemiologic study of mortality for the period 1954-1976. They found no suggestion of an increased rate of cancer, hepatic, or renal disease among the anesthesiologists. Also

in 1979, a study[9] of infants born in 1973 or 1975 to Swedish women working in operating rooms during their pregnancies was published. There was no increased incidence of abortions, or congenital malformations found. The negative findings of the Swedish study have been attributed to their use of unbiased records rather than the mail questionnaires used by the other studies which reported health problems among operating room personnel.

The original studies of Cohen[10], Bruce[11], and Corbett[12], to name a few, are being questioned, but the extent to which the waste anesthetic agents present a health hazard has not been conclusively demonstrated.

Due to the controversy, many hospitals conservatively decided to install scavenging devices in the operating rooms to reduce the concentration of waste anesthetic agents. As of 1977, 65-75% of all operating rooms in the United States had begun using scavenging devices which trap waste gas at leakage points and remove it from the operating room[2]. Air sampling studies in these scavenged operating rooms indicate that the waste anesthetic agent time weighed average concentration ranges from 0.2 ppm to 2.0 ppm for halogenated agents and from seven ppm to 165 ppm for nitrous oxide[13-18]. However, in 25-35% of all operating rooms, scavenging devices are not used. The literature reports operating room personnel exposures in these rooms ranging from one to 199 ppm peak Halothane concentrations and from 400 to 9700 ppm for nitrous oxide[19-22].

Prior to June 1980, the recommended criteria for exposure to waste anesthetic agents was contained in the NIOSH Criteria Document[2]. The recommendation was that no worker was to be exposed to concentrations greater than 2.0 ppm for a halogenated anesthetic agent. However, in late May 1980, the American Conference of Governmental Industrial Hygienists Threshold Limit Value (TLV) Committee published the notice of intended TLV changes for 1980[23]. The notice adds nine chemicals to the TLV list. Halothane is on the TLV list with an eight hour time weighed average concentration of 50 ppm (400 milligrams/cubic meter). A short term exposure level is not given.

Great strides have been made in reducing the anesthetic agent concentration in the operating room by following the advise of Whitcher[24], Bruce[25], and McInnes[26], to name a few. But, as Snow reports[27], no system for the removal of waste anesthetic agents is 100% effective. Consequently, operating room personnel will continue to be exposed to some trace amounts of anesthetic agents no matter how much the anesthesiologists improve their techniques or how well the hospital maintenance sections prevent leaks from the anesthesia carts.

Without definitive evidence that anesthetic agents do or do not pose a health hazard, it is prudent to presume that a risk exists even at trace concentrations. Consequently, an effort must be made to reduce the amount of waste agent breathed by operating room personnel. Kim[28] reported that activated charcoal adsorbs Halothane vapor very well. Since the 3M #8711 respirator is impregnated with activated

charcoal, it can be hypothesized that the use of the respirator can reduce an individual's exposure to Halothane vapors.

Therefore, the following hypotheses are stated:

Null Hypothesis I $H_o: \mu_{peak} \geq 50$ ppm (the population mean peak concentration inside the respirator when challenged with approximately 140 ppm of Halothane in air for 7.25 hours is greater than or equal to 50 ppm.)

Alternative Hypothesis I $H_a: \mu_{peak} < 50$ ppm (the population mean peak concentration is less than 50 ppm.)

Null Hypothesis II $H_o: \mu_{TWA} \geq 50$ ppm (the population mean time weighed average concentration inside the respirator when challenged with approximately 140 ppm of Halothane in air for 7.25 hours is greater than or equal to 50 ppm.)

Alternative Hypothesis II $H_a: \mu_{TWA} < 50$ ppm (the population mean time weighed average concentration is less than 50 ppm)

# METHODOLOGY

This research was designed to determine if the 3M #8711 respirator, when challenged with approximately 140 parts per million (ppm) of Halothane in air for 7.25 hours, would keep the peak and time weighed average Halothane concentration inside of the respirator below 50 ppm, the Threshold Limit Value.

## The Test Chamber

The research was conducted using a test chamber located at the School of Aerospace Medicine, Brooks Air Force Base, San Antonio, Texas. The test chamber is a modification of a rebreathing system patented by members of the School of Aerospace Medicine (patent number 3,951,137). The rebreatning system was modified as necessary to meet the needs of the research. A schematic diagram of the modified system is provided in Figure 1. A photograph of the experimental equipment is provided in Figure 2.

The concentration of the Halothane challenge atmosphere outside of the respirator was controlled by a closed loop Halothane generation system composed of a MIRAN Infrared Analyzer, an electronic controller, a small pump, and a fritted glass bubbler filled with liquid Halothane.

The MIRAN continuously monitored the concentration of the Halothane challenge atmosphere. The MIRAN has a 0-1 volt output terminal. The electronic controller was connected to that output. The controller was

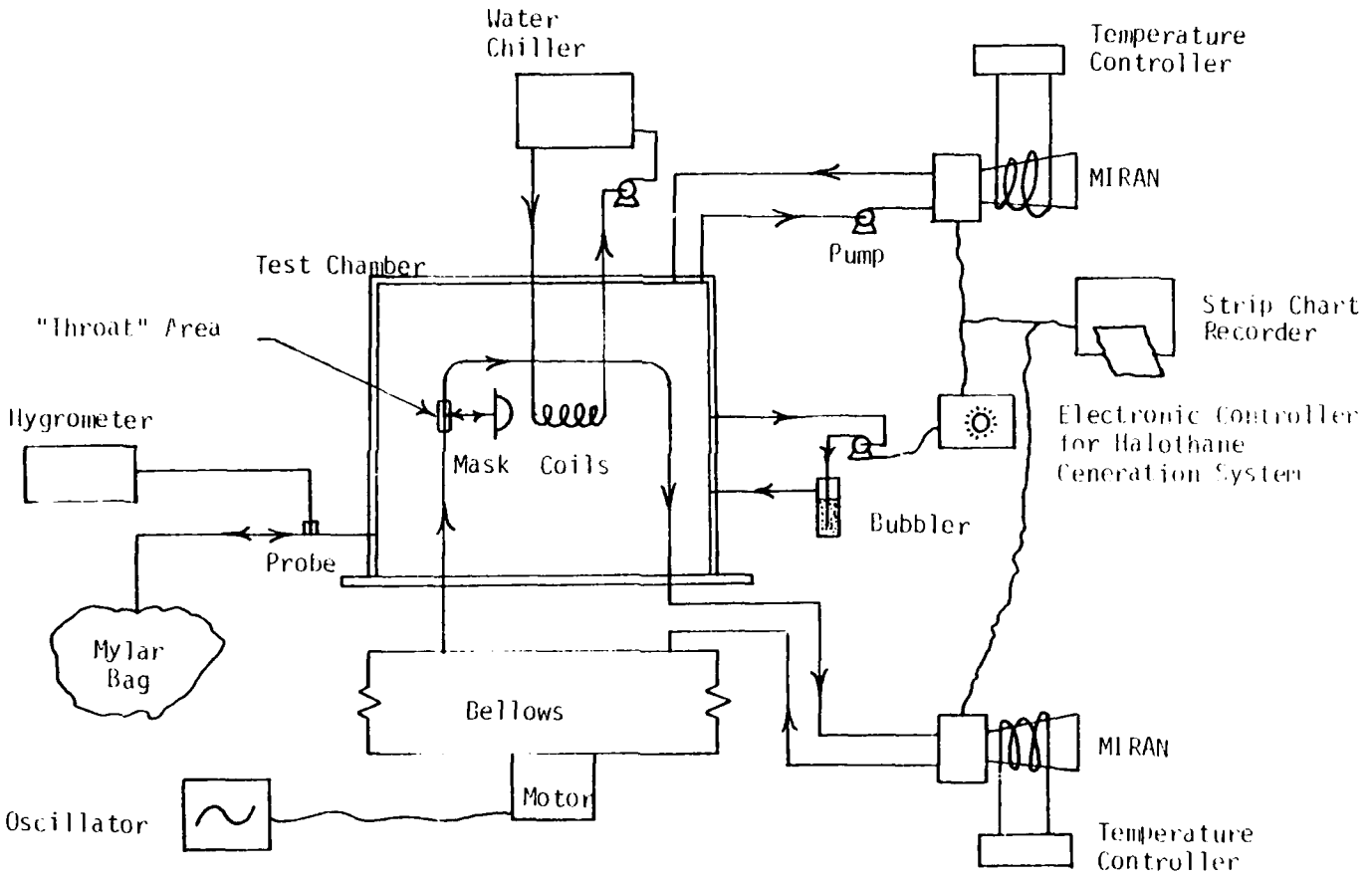


Figure 1--Schematic diagram showing basic components of the research apparatus.

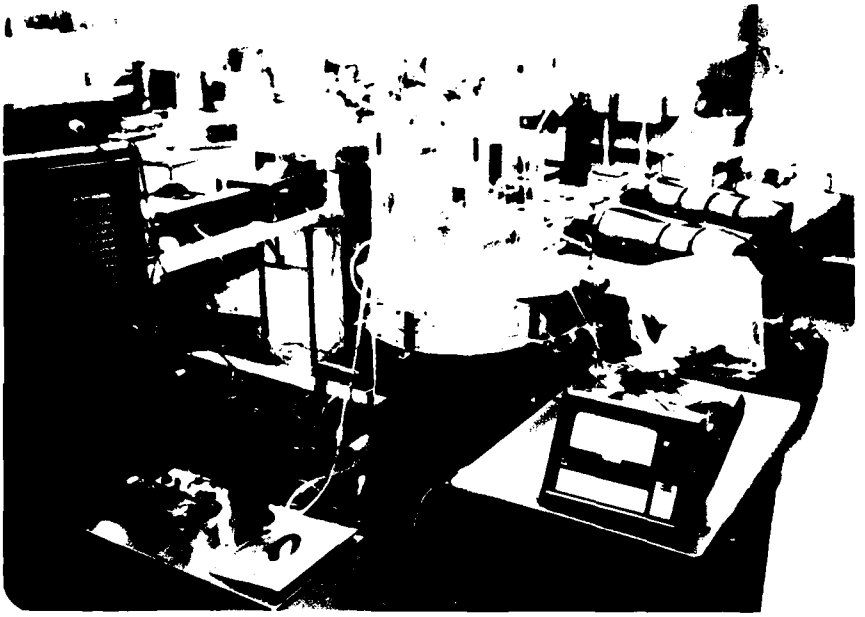

Figure 2--Photograph of the research apparatus.

a simple switching device which could be set to activate the small pump when a selected voltage level of the MIRAN output was reached. Consequently, as the Halothane challenge concentration in the test chamber decreased, the MIRAN meter reading and output voltage also decreased. As the voltage fell below the level set on the controller, the controller activated the small pump. The pump was connected to a fritted glass bubbler filled with liquid Halothane. The liquid Halothane was vaporized as the air bubbled through the liquid. The vapor was injected into the test chamber. As the Halothane challenge concentration increased, the MIRAN meter reading and output voltage also increased. As the voltage rose above the level set on the controller, the controller deactivated the small pump and the injection of Halothane into the test chamber ceased. This cycle was repeated automatically to generate a uniform challenge atmosphere.

An open loop Halothane generation system was initially used. However, the system used too much liquid Halothane and could not be left unattended for any appreciable length of time. Such a system may be of interest to the reader for other applications and is discussed in detail in Appendix A.

The concentration of the Halothane that broke through the respirator was monitored by another MIRAN that was connected to the bellows. The bellows simulated human lungs. As the bellows moved downward (inspiration), the decrease in pressure in the bellows caused the air in the upper plexiglass chamber to flow into the respirator and

through the pipes toward the bellows. As the bellows moved upward (expiration), the increase in pressure in the bellows pushed the air out through the respirator.

By using a set of one-way valves in the "throat" section of the pipe system, the bellows' compression/expansion action pumped the air through the MIRAN which was to monitor for Halothane that broke through the respirator. Consequently, any Halothane that broke through the respirator would first travel to the MIRAN before reaching the bellows. Figures 3 and 4 show how the one-way valves kept the air flowing in one direction.

Each inspiration/expiration cycle of the bellows caused a transfer of air between the plexiglass upper chamber and the lower bellows chamber. To prevent the rigid walled chambers from experiencing compression/expansion stresses, a mylar bag was attached to the plexiglass chamber. Therefore, the mylar bag inflated/deflated with each bellows movement and the stress on the system was eliminated.

To control the humidity in the challenge atmosphere inside the plexiglass upper chamber, chilled water was pumped through coiled copper tubing. Figure 5 shows a photograph of the test chamber with the tubing in place. The humidity in the challenge atmosphere was kept at approximately 60% relative humidity. To monitor the humidity of the challenge atmosphere, a hygrometer probe was placed near the mylar bag. The location of the hygrometer probe is shown in Figure 1.

To help reduce the formation of moisture on the lens inside of the

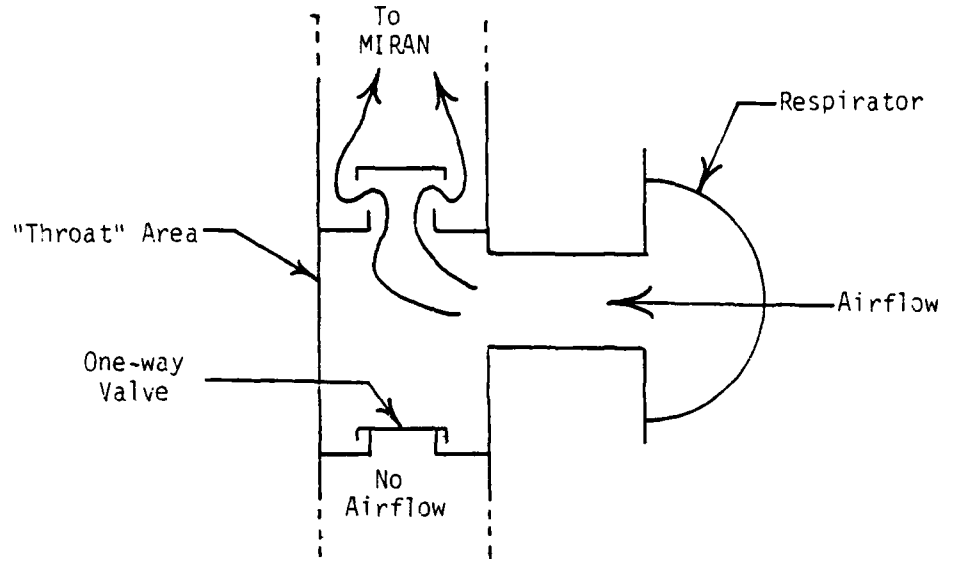


Figure 3--Position of one-way valves
in throat area during inspiration.

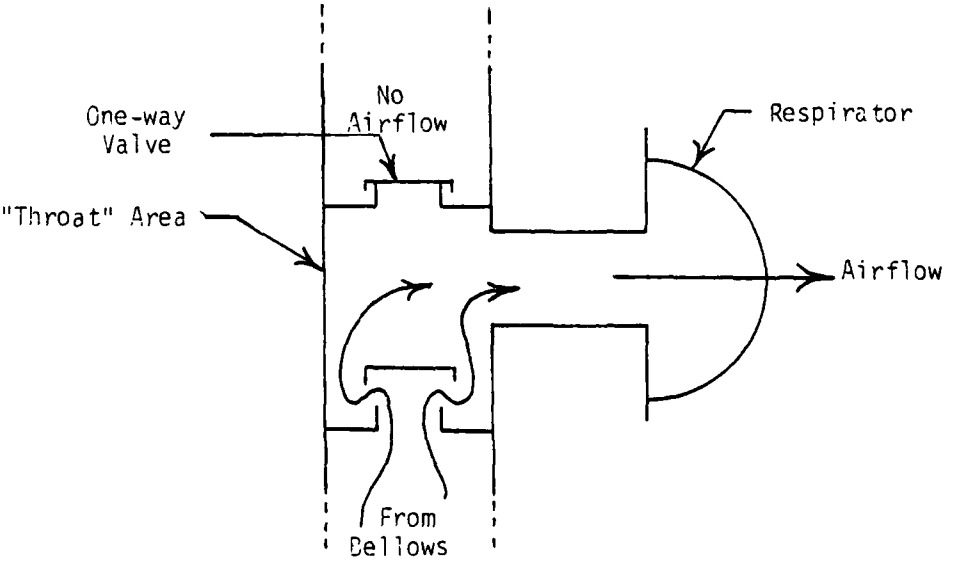


Figure 4--Position of one-way valves
in throat area during expiration.

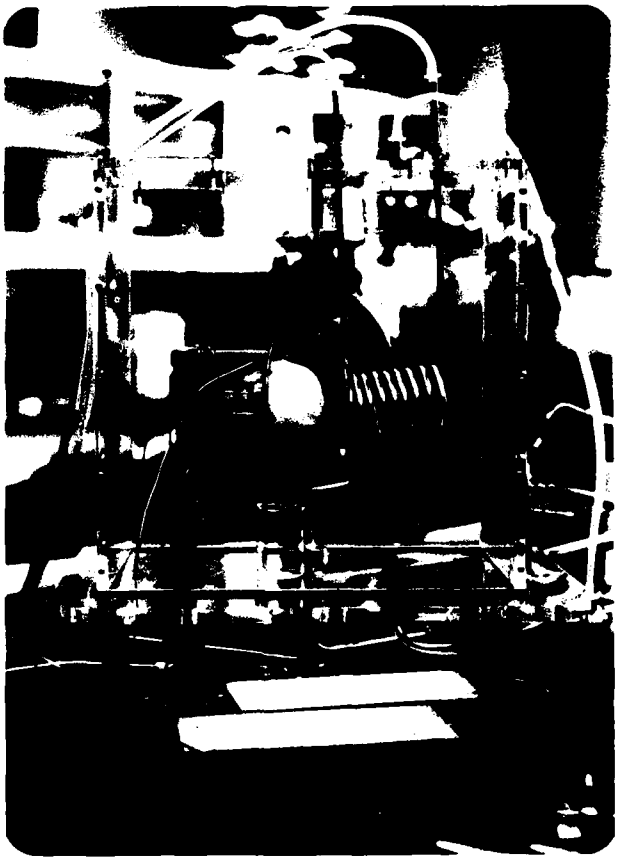

Figure 5--Photograph showing the cooling coils used to control the humidity in the test chamber.

MIRAN, each MIRAN was wrapped with a heater blanket to keep the MIRAN chamber heated at about 50°C. Figure 6 shows a MIRAN wrapped in the heater blanket. Heaters were also used to warm the bellows chamber to 37°C. Therefore, the exhalation breath from the bellows chamber simulated the breath temperature of a human.

Each 3M #8711 respirator was used as received from the manufacturer except that the straps and strap holders were removed. The edge of the respirator was secured to the metal facepiece by an oval strip of metal to prevent air leakage around the facepiece and respirator. The intent of this design was to eliminate the problem of variability of respirator fit on an individual's face.

## Calibration of MIRAN Monitors

The MIRAN analyzers were calibrated using a closed loop set-up shown in Figure 7. Various microliter amounts of liquid Halothane were injected into the system and the absorbance recorded. Calibration curves were established at three pathlengths to provide absorbances for the range of Halothane concentrations expected during the experimental period. Appendix B provides an example of the calibration procedure.

## Calibration of Bellows Volume

The electronics which controlled the operation of the bellows'

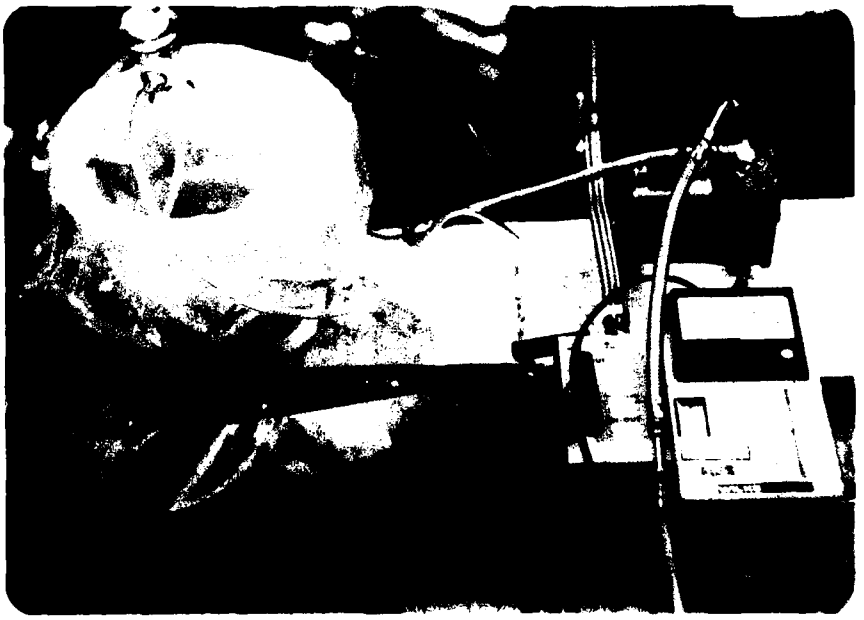

Figure 6--Photograph showing the MIRAN wrapped with a heater blanket.

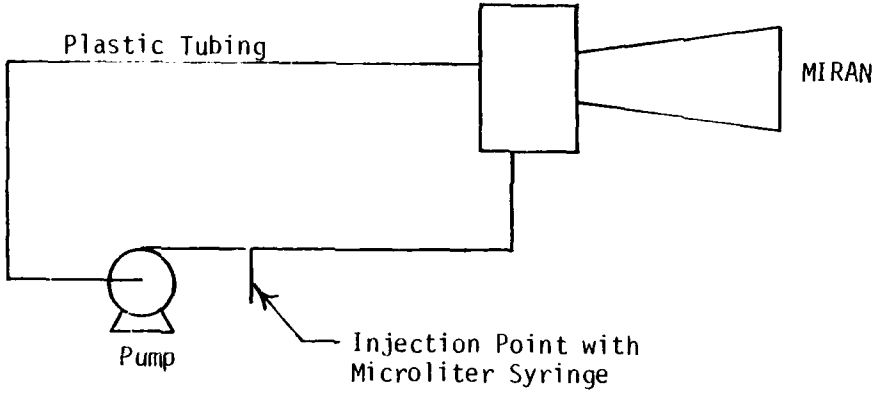


Figure 7-- Closed loop calibration system.

motor were housed in a metal control panel. Included in the panel was a digital readout which displayed the volume of air displaced with each bellows stroke. The system was calibrated using a nine liter capacity respirometer. The bellows was connected to the respirometer. The bellows was permitted to travel from its fully expanded position (maximum volume of air in the bellows), to its fully compressed position (minimum volume of air in the bellows). The volume of air displaced was obtained using the respirometer and the digital readout on the control panel was adjusted to read that volume difference.

## Selection of Breath Volume and Rate

To conduct the respirator experiments, a breathing rate and breath volume had to be selected. As currently constructed, the bellows total volume change (breath volume) and number of volume changes per minute (breathing rate) interact. That is, if one wants the bellows to simulate rapid breathing, the depth of the breath is fixed. The bellows can breath rapidly only if the breaths are shallow. Rapid deep breaths are not possible. As the number of breaths per minute is decreased, deeper and deeper breaths are possible.

Although the Bendix study recommended a respiration rate of 24 breaths per minute and a volume of 40 liters per minute (L/min) to study valveless respirators, the bellows used for this research was not able to reach those rates. Bendix reported that those rates are representative of a human at a median work rate. However, operating

room personnel will not be breathing at those rates. The American Conference of Governmental Industrial Hygienists reports[29] that an average metabolic rate for a person who is standing and working with both arms is approximately four kilocalories per minute (kcal/min). McCormick[30] reports that an individual's oxygen uptake is related to the amount of work performed expressed in kcal/min. For four kcal/min of work, the oxygen uptake is approximately one L/min. Astrand[31] reports that oxygen uptake is related to the pulmonary ventilation rate. For one L/min oxygen uptake, the pulmonary ventilation rate is approximately 20 L/min.

When the bellows is set to breathe 15 breaths per minute, the depth of each breath is approximately 1.29 liters. This breathing rate/depth combination results in a ventilation rate of 19.35 L/min and was used for this research.

## Selection of a Halothane Challenge Atmosphere Concentration

Based on the Bendix report, it was apparent that each experiment of this research could be very time consuming if a very low challenge concentration was selected. Consequently, to accelerate the breakthrough of the Halothane, it was desirable to select a concentration which represented a "worst case" situation.

Table XIII-2 of the NIOSH Criteria Document for waste anesthetic gases and vapors[2] reports one case where the concentration of Halothane

in the general air of an operating room was 199 ppm. This concentration was a peak value rather than a time weighed average. None of the other Halothane exposures reported in the document were over 100 ppm. In addition, a review of 137 operating room air samples analyzed for Halothane by the U.S. Air Force Occupational and Environmental Health Laboratory at Brooks AFB, Texas in 1979 and part of 1980 reveals that most Halothane exposures were less than 10 ppm. Table I lists the distribution of Air Force samples in the various concentration groups.

Table I

Grouped Data of Air Samples Analyzed for Halothane by the U.S. Air Force Occupational and Environmental Health Laboratory

| *Halothane* Concentration Range (ppm) | Number of Samples | Percent of Total |
|---|---|---|
| None Detected - 10 | 119 | 86.86 |
| 10-40 | 12 | 8.76 |
| 40-80 | 3 | 2.19 |
| 80-120 | 2 | 1.46 |
| 120-160 | 1 | 0.73 |

Based on this data, a Halothane concentration of approximately 140 ppm is considered a "worst case" challenge concentration for this research.

## Basic Experimental Procedure

Five respirators were exposed to the challenge Halothane atmosphere. Prior to each experiment, the bellows chamber and MIRAN analyzers were flushed with fresh air. In addition, the MIRAN analyzers were properly zeroed. An unused respirator was installed on the facepiece and the plexiglass box cover placed over the base plate to seal the challenge atmosphere test chamber. The dual strip chart was placed into operation and Halothane generation system turned on. As the challenge atmosphere reached the desired concentration, the bellows was energized and the start time recorded. As time progressed, the concentration of Halothane inside of the respirator built up. The strip chart recorded the MIRAN absorbance levels as a function of time. Figure 8 is a strip chart result for an experiment with a challenge concentration of 3000 ppm Halothane. This particular strip chart is shown because the MIRAN's response to the Halothane build up inside of the respirator is concise and can fit on one page.

Note on the figure that the challenge concentration oscillates in a constant manner as the controller periodically alters the Halothane generation system from an operational to a non-operational mode. Also note that the concentration inside of the respirator begins at zero parts per million and steadily increases as time passes. Using the appropriate calibration curve, the absorbance values can be converted into concentration (ppm) values. Knowing the concentration of the

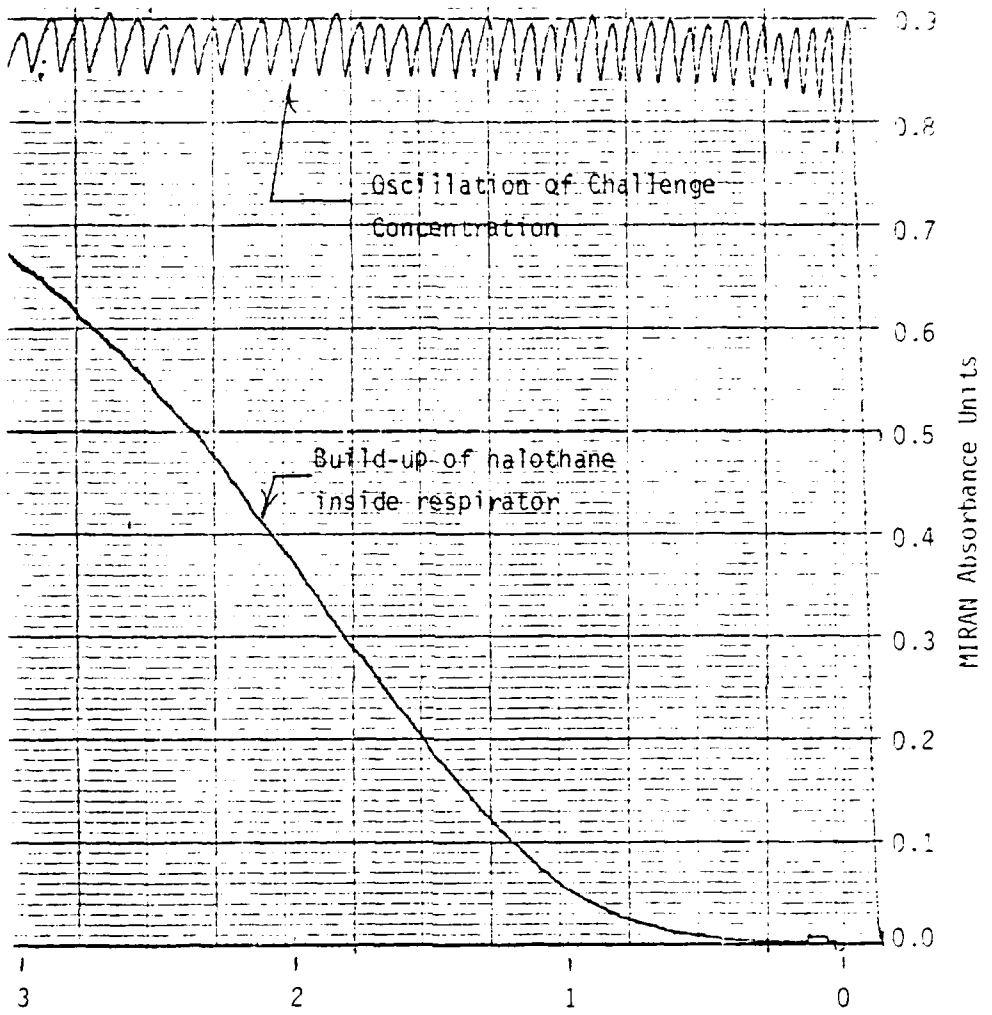


Figure 8--A typical strip chart result during respirator testing.

challenge atmosphere, a percent breakthrough (percent of challenge concentration) can be computed for any time point during the experiment.

## Statistical Analysis of Data

For each of the five experiments, the halothane concentration inside of the respirator was noted 7.25 hours after the exposure began. This exposure time was chosen because three experiments were planned for each day and 45 minutes were needed for equipment preparation between each experiment.

With this data, the sample variance and bound on the error of estimation were computed. In addition, for each experiment, the time weighed average concentration inside of the respirator was computed. T-tests were performed to determine if the population mean peak concentration and/or population mean time weighed average concentration inside of the respirator was below 50 ppm.

# RESULTS

Raw data for the five experiments are shown on Tables II-VII. The results of the experiments are graphically presented in Figures 9 to 15.

Figure 9 is a plot of the amount of Halothane that penetrated the respirator as percent breakthrough (i.e., as a percent of the challenge concentration) versus time. The same data plotted on log-log paper is presented as Figure 10. The percent breakthrough as a function of the cumulative ppm-hours inside of the mask is shown as Figure 11. Figure 12 is a plot of the amount of Halothane that penetrated the respirator as a ppm concentration versus time. The data shown in Figure 12 was averaged and Figure 13 is a plot of this average penetration versus time graph. The graph uses bars to indicate one standard deviation from the average. Figure 14 is a plot of the average cumulative ppm-hours inside of the respirator as a function of time. Bars are used to indicate one standard deviation from the average. Figure 15 is a plot of the average of the time weighed average concentrations as a function of time. Bars are used to indicate one standard deviation from the average.

The statistical analysis of the data at 7.25 hours of exposure to the challenge agent is derived and calculated in Appendix C. After 7.25 hours of exposure, the peak concentration of Halothane inside of the respirator ranged from 14 to 24 ppm. The sample mean was 18.6 ppm.

Table II

Data From Experiment A

| Exposure Time (hrs) | MIRAN Absorbance* | Concentration (ppm)** | Incremental ppm-hours*** | Cumulative ppm-hours | ppm-hours of the challenge | Percent Breakthrough |
|---|---|---|---|---|---|---|
| 0.0 | 0.000 | 0.0 | 0.00 | 0.00 | 0 | 0.00 |
| 2.5 | 0.000 | 0.0 | 0.00 | 0.00 | 345 | 0.00 |
| 3.0 | 0.005 | 0.5 | 0.12 | 0.12 | 414 | 0.36 |
| 3.5 | 0.012 | 1.3 | 0.45 | 0.57 | 483 | 0.94 |
| 4.0 | 0.020 | 2.1 | 0.85 | 1.42 | 552 | 1.52 |
| 4.5 | 0.032 | 3.4 | 1.37 | 2.80 | 621 | 2.46 |
| 5.0 | 0.047 | 4.9 | 2.07 | 4.87 | 690 | 3.55 |
| 5.5 | 0.070 | 7.3 | 3.05 | 7.90 | 759 | 5.28 |
| 6.0 | 0.095 | 9.9 | 4.30 | 12.2 | 828 | 7.17 |
| 6.5 | 0.127 | 13.5 | 5.85 | 18.00 | 897 | 9.78 |
| 7.0 | 0.167 | 19.5 | 8.25 | 26.30 | 966 | 14.13 |
| 7.25 | 0.180 | 21.0 | 5.06 | 31.30 | 1000 | 15.21 |

* MIRAN Absorbance of Challenge Atmosphere at 20.25 Meter Pathlength/12.3 uM wavelength = 0.955 A

** Concentration of Challenge Atmosphere = 138 ppm

*** Area under ppm-time curve since last exposure time increment.

Table III

Data From Experiment B

| Exposure Time (hrs) | MIRAN Absorbance* | Concentration (ppm)** | Incremental ppm-hours*** | Cumulative ppm-hours | ppm-hours of the Challenge | Percent Breakthrough |
|---|---|---|---|---|---|---|
| 0.0 | 0.000 | 0.0 | 0.00 | 0.00 | 0 | 0.00 |
| 1.5 | 0.000 | 0.0 | 0.00 | 0.00 | 214 | 0.00 |
| 2.0 | 0.005 | 0.5 | 0.12 | 0.12 | 286 | 0.34 |
| 2.5 | 0.010 | 1.0 | 0.37 | 0.50 | 357 | 0.69 |
| 3.0 | 0.015 | 1.5 | 0.62 | 1.12 | 429 | 1.04 |
| 3.5 | 0.025 | 2.6 | 1.02 | 2.15 | 500 | 1.80 |
| 4.0 | 0.040 | 4.2 | 1.70 | 3.85 | 572 | 2.91 |
| 4.5 | 0.055 | 5.7 | 2.47 | 6.32 | 643 | 3.95 |
| 5.0 | 0.077 | 8.1 | 3.45 | 9.77 | 715 | 5.62 |
| 5.5 | 0.105 | 10.9 | 4.75 | 14.52 | 786 | 7.56 |
| 6.0 | 0.13 | 14.0 | 6.22 | 20.75 | 858 | 9.72 |
| 6.5 | 0.16 | 18.5 | 8.12 | 28.87 | 929 | 12.84 |
| 7.0 | 0.19 | 23.0 | 10.37 | 39.25 | 1001 | 15.97 |
| 7.25 | 0.20 | 24.0 | 5.87 | 45.12 | 1036 | 16.66 |

* MIRAN Absorbance of Challenge Atmosphere at 20.25 Meter Pathlength/12.3 uM wavelength = 0.99 A

** Concentration of Challenge Atmosphere = 144 ppm

*** Area under ppm-time curve since last exposure time increment.

Table IV

Data From Experiment C

| Exposure Time (hrs) | MIRAN Absorbance* | Concentration (ppm)** | Incremental ppm-hours*** | Cumulative ppm-hours | ppm-hours of the Challenge | Percent Breakthrough |
|---|---|---|---|---|---|---|
| 0.0 | 0.000 | 0.0 | 0.00 | 0.00 | 0 | 0.00 |
| 1.5 | 0.000 | 0.0 | 0.00 | 0.00 | 208 | 0.00 |
| 2.0 | 0.005 | 0.5 | 0.12 | 0.12 | 278 | 0.36 |
| 2.5 | 0.015 | 1.5 | 0.50 | 0.62 | 347 | 1.07 |
| 3.0 | 0.020 | 2.1 | 0.90 | 1.52 | 417 | 1.51 |
| 3.5 | 0.030 | 3.1 | 1.30 | 2.82 | 486 | 2.23 |
| 4.0 | 0.042 | 4.4 | 1.80 | 4.70 | 556 | 3.16 |
| 4.5 | 0.055 | 5.7 | 2.50 | 7.22 | 625 | 4.10 |
| 5.0 | 0.070 | 7.3 | 3.20 | 10.47 | 695 | 5.25 |
| 5.5 | 0.085 | 8.9 | 4.00 | 14.52 | 764 | 6.40 |
| 6.0 | 0.100 | 10.4 | 4.80 | 19.35 | 834 | 7.48 |
| 6.5 | 0.115 | 12.0 | 5.60 | 24.95 | 903 | 8.63 |
| 7.0 | 0.120 | 12.5 | 6.10 | 31.07 | 973 | 8.99 |
| 7.25 | 0.130 | 14.0 | 3.30 | 34.38 | 1007 | 10.07 |

* MIRAN Absorbance of Challenge Atmosphere at 20.25 Meter Pathlength/12.3 uM wavelength = 0.96 A

** Concentration of Challenge Atmosphere = 139 ppm

*** Area under ppm-time curve since last exposure time increment.

Table V

Data From Experiment D

| Exposure Time (hrs) | MIRAN Absorbance* | Concentration (ppm)** | Incremental ppm-hours*** | Cumulative ppm-hours | ppm-hours of the Challenge | Percent Breakthrough |
|---|---|---|---|---|---|---|
| 0.0 | 0.000 | 0.0 | 0.00 | 0.00 | 0 | 0.00 |
| 2.5 | 0.000 | 0.0 | 0.00 | 0.00 | 342 | 0.00 |
| 3.0 | 0.005 | 0.5 | 0.12 | 0.12 | 411 | 0.36 |
| 3.5 | 0.012 | 1.3 | 0.45 | 0.57 | 479 | 0.94 |
| 4.0 | 0.020 | 2.1 | 0.85 | 1.42 | 548 | 1.53 |
| 4.5 | 0.030 | 3.1 | 1.30 | 2.72 | 616 | 2.26 |
| 5.0 | 0.045 | 4.7 | 1.95 | 4.67 | 685 | 3.43 |
| 5.5 | 0.060 | 6.2 | 2.72 | 7.40 | 753 | 4.52 |
| 6.0 | 0.080 | 8.3 | 3.62 | 11.02 | 822 | 6.05 |
| 6.5 | 0.105 | 10.9 | 4.80 | 15.82 | 890 | 7.95 |
| 7.0 | 0.130 | 14.0 | 6.22 | 22.05 | 959 | 10.21 |
| 7.25 | 0.145 | 16.5 | 3.81 | 25.86 | 993 | 12.04 |

* MIRAN Absorbance of Challenge Atmosphere at 20.25 Meter Pathlength/12.3 uM wavelength = 0.95 A

** Concentration of Challenge Atmosphere = 137 ppm

*** Area under ppm-time curve since last exposure time increment.

Table VI

Data From Experiment E

| Exposure Time (hrs) | MIRAN Absorbance* | Concentration (ppm)** | Incremental ppm-hours*** | Cumulative ppm-hours | ppm-hours of the Challenge | Percent Breakthrough |
|---|---|---|---|---|---|---|
| 0.0 | 0.000 | 0.0 | 0.00 | 0.00 | 0 | 0.00 |
| 0.5 | 0.000 | 0.00 | 0.00 | 0.00 | 68 | 0.00 |
| 1.0 | 0.005 | 0.5 | 0.12 | 0.12 | 137 | 0.36 |
| 1.5 | 0.007 | 0.8 | 0.32 | 0.45 | 205 | 0.58 |
| 2.0 | 0.015 | 1.5 | 0.57 | 1.02 | 274 | 1.09 |
| 2.5 | 0.022 | 2.3 | 0.95 | 1.97 | 342 | 1.67 |
| 3.0 | 0.035 | 3.6 | 1.47 | 3.45 | 411 | 2.62 |
| 3.5 | 0.050 | 5.2 | 2.20 | 5.65 | 479 | 3.79 |
| 4.0 | 0.060 | 6.3 | 2.87 | 8.52 | 548 | 4.59 |
| 4.5 | 0.075 | 7.8 | 3.52 | 12.05 | 616 | 5.69 |
| 5.0 | 0.092 | 9.6 | 4.35 | 16.40 | 685 | 7.00 |
| 5.5 | 0.105 | 10.9 | 5.12 | 21.52 | 753 | 7.95 |
| 6.0 | 0.120 | 12.5 | 5.85 | 27.37 | 822 | 9.12 |
| 6.5 | 0.135 | 14.5 | 6.75 | 34.12 | 890 | 10.58 |
| 7.0 | 0.145 | 16.5 | 7.75 | 41.87 | 959 | 12.04 |
| 7.25 | 0.155 | 17.5 | 4.25 | 46.12 | 993 | 12.77 |

* MIRAN Absorbance of Challenge Atmosphere at 20.25 Meter Pathlength/12.3 uM wavelength = 0.95 A

** Concentration of Challenge Atmosphere = 137 ppm

*** Area under ppm-time curve since last exposure time increment.

Table VII

Summary of Time Weighed Average Concentration Data

| Exposure Time (hrs) | Parts per Million Time Weighed Average (TWA) Concentration for each Experiment | | | | | Average of TWA Concentrations |
|---|---|---|---|---|---|---|
| | Experiment A | Experiment B | Experiment C | Experiment D | Experiment E | |
| 0.0 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 0.5 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 1.0 | 0.00 | 0.00 | 0.00 | 0.00 | 0.12 | 0.02 |
| 1.5 | 0.00 | 0.00 | 0.00 | 0.00 | 0.30 | 0.06 |
| 2.0 | 0.00 | 0.06 | 0.06 | 0.00 | 0.51 | 0.12 |
| 2.5 | 0.00 | 0.20 | 0.25 | 0.00 | 0.79 | 0.24 |
| 3.0 | 0.04 | 0.37 | 0.50 | 0.04 | 1.15 | 0.42 |
| 3.5 | 0.16 | 0.61 | 0.80 | 0.16 | 1.61 | 0.67 |
| 4.0 | 0.35 | 0.96 | 1.17 | 0.35 | 2.13 | 0.99 |
| 4.5 | 0.62 | 1.40 | 1.60 | 0.60 | 2.67 | 1.38 |
| 5.0 | 0.97 | 1.95 | 2.09 | 0.93 | 3.28 | 1.84 |
| 5.5 | 1.44 | 2.64 | 2.64 | 1.34 | 3.91 | 2.39 |
| 6.0 | 2.03 | 3.45 | 3.22 | 1.83 | 4.56 | 3.01 |
| 6.5 | 2.78 | 4.44 | 3.83 | 2.43 | 5.25 | 3.74 |
| 7.0 | 3.76 | 5.60 | 4.43 | 3.15 | 5.98 | 4.58 |
| 7.25 | 4.32 | 6.22 | 4.74 | 3.56 | 6.36 | 5.04 |

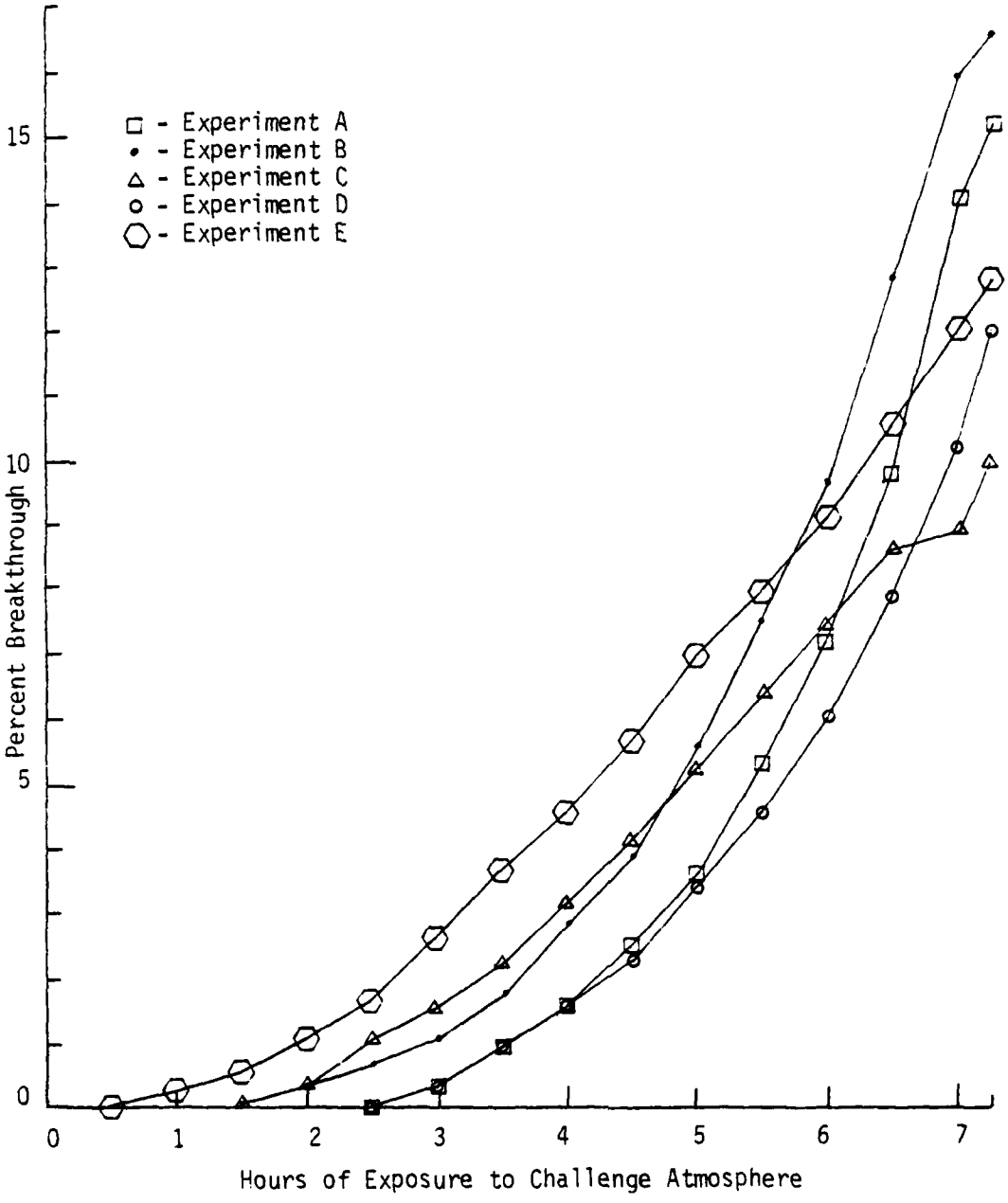


Figure 9--Percent breakthrough versus exposure time, 2-way airflow.

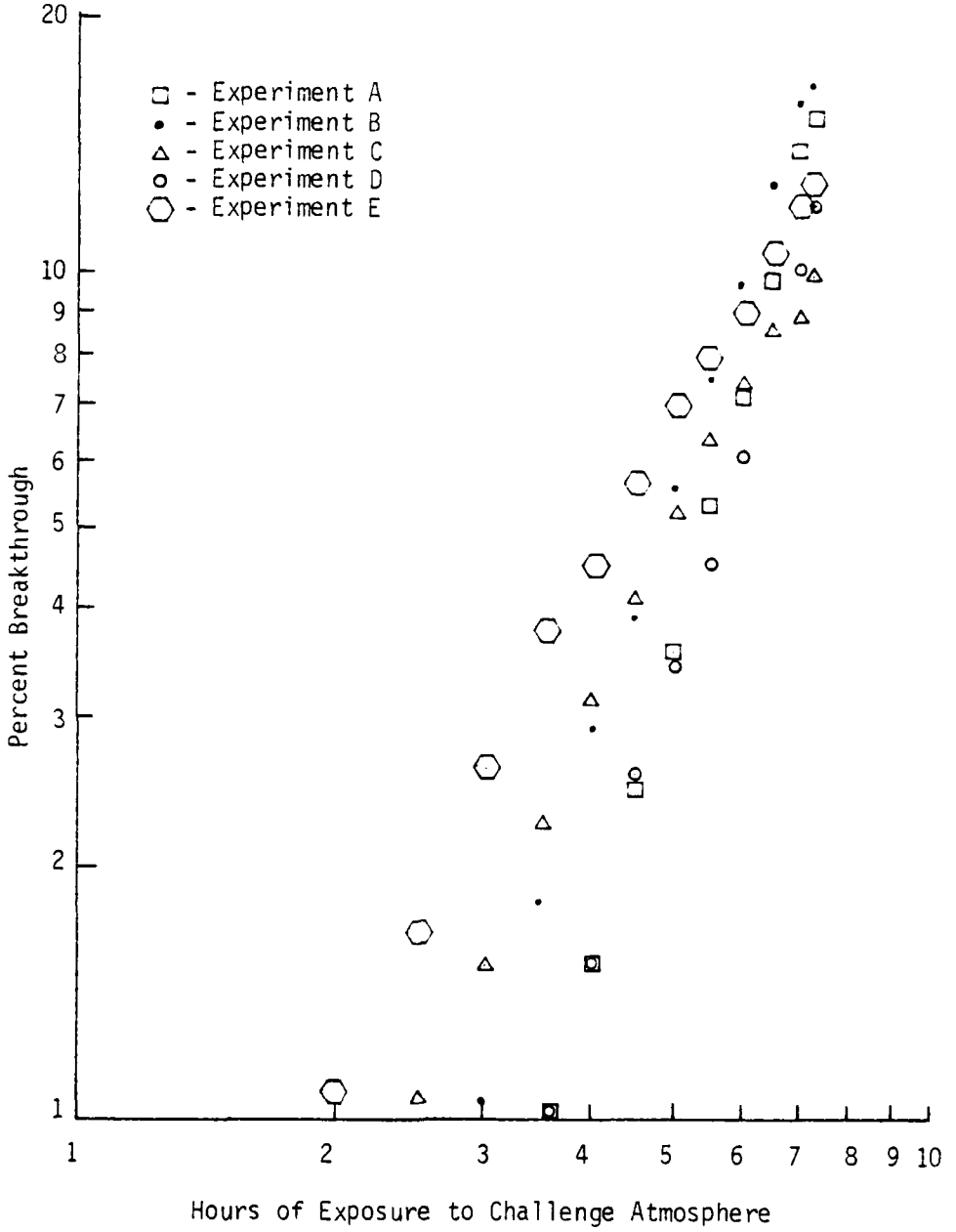


Figure 10--Percent breakthrough versus exposure time, 2-way airflow, log-log graph.

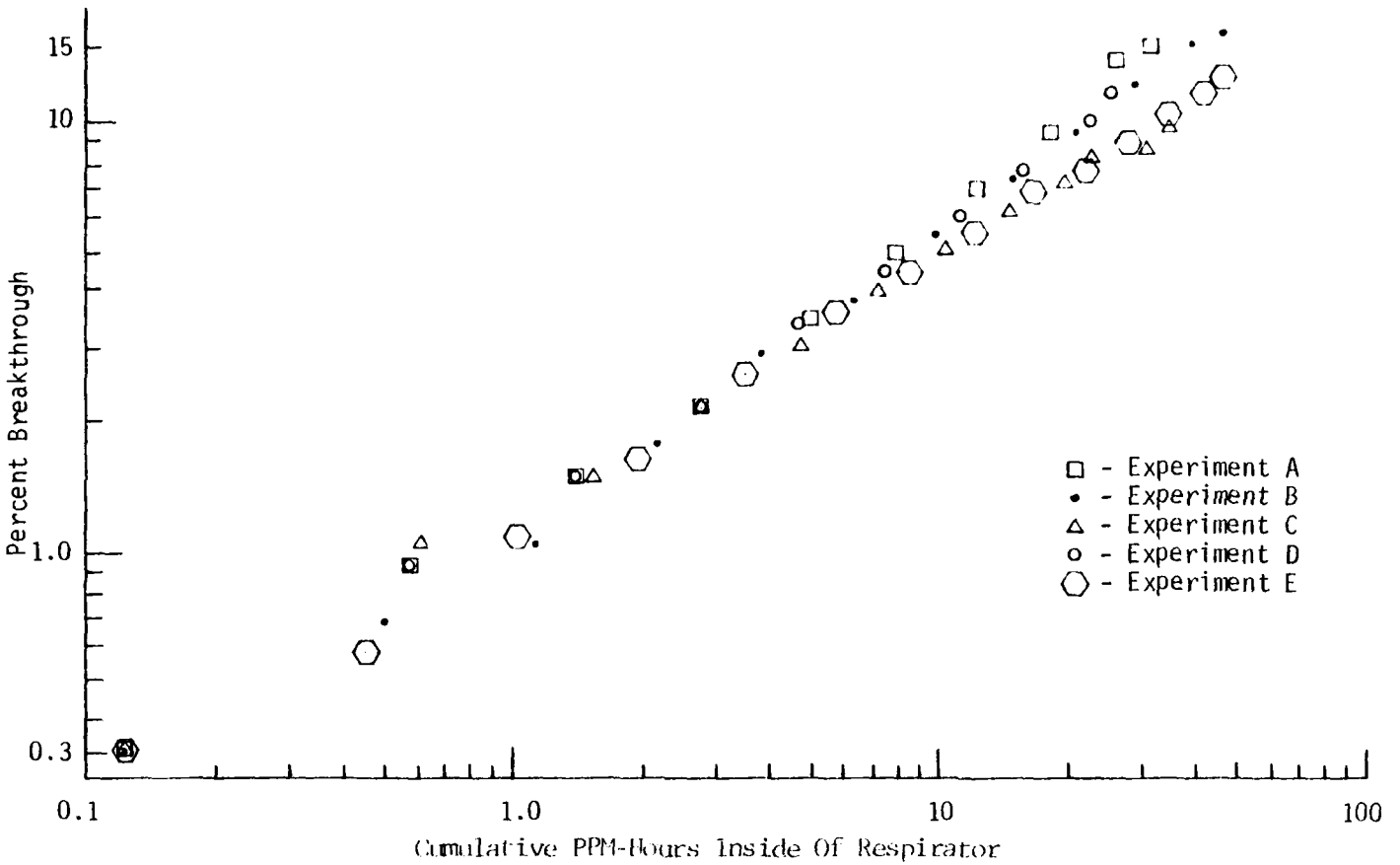


Figure 11--Percent breakthrough versus cumulative PPM-Hours inside respirator.

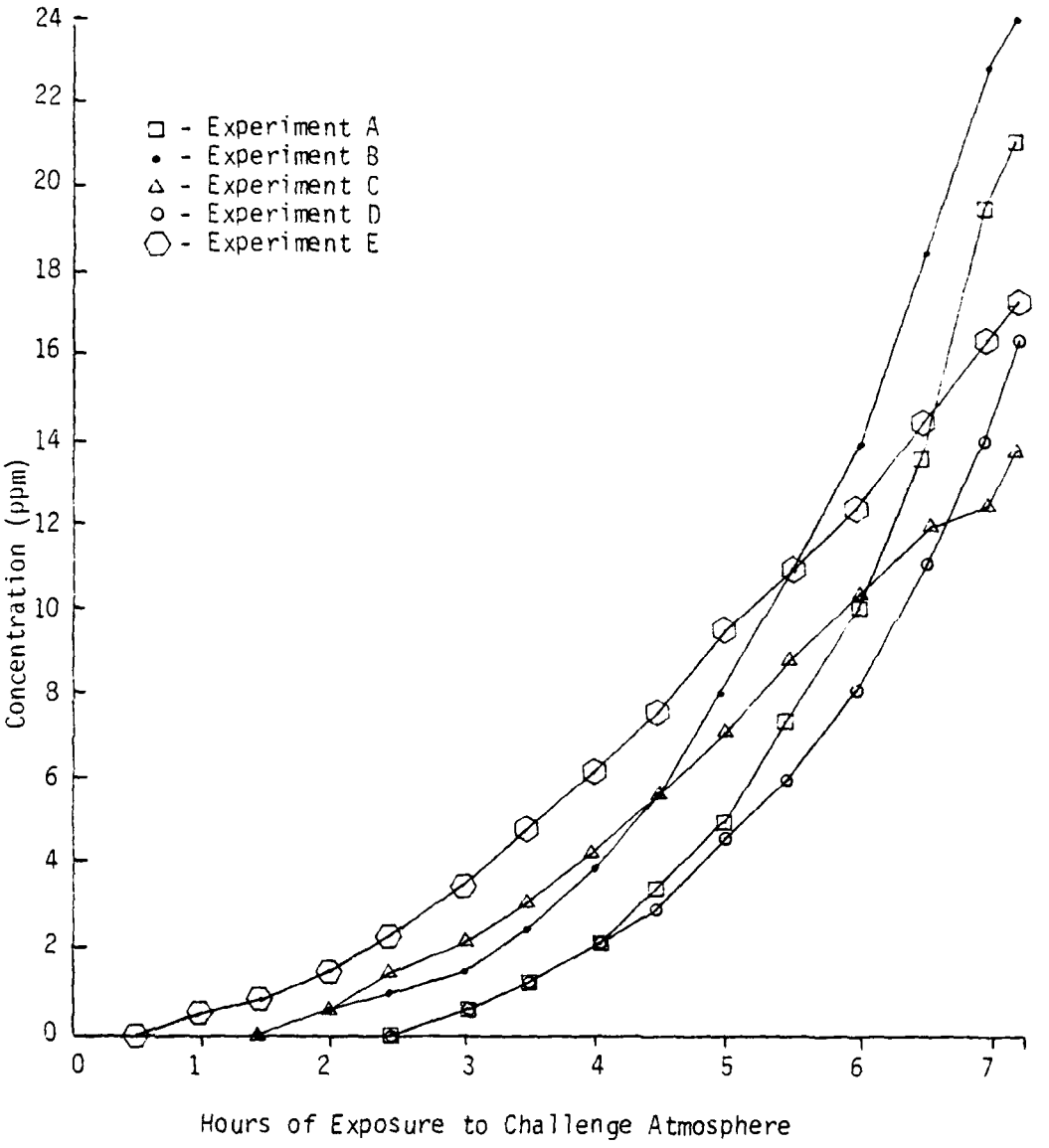


Figure 12--Peak concentration inside mask versus exposure time.

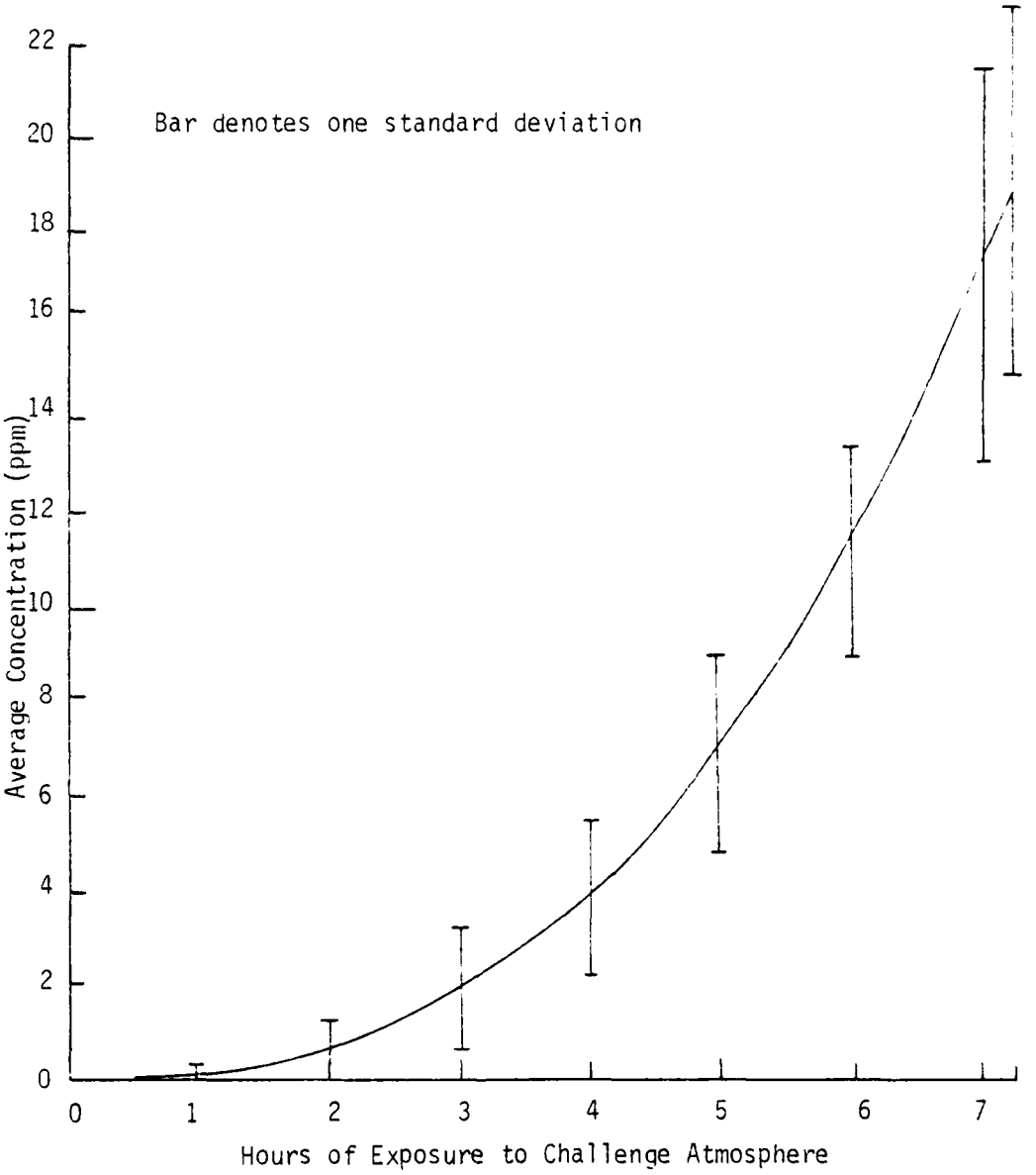


Figure 13--Average of peak concentrations inside respirators.

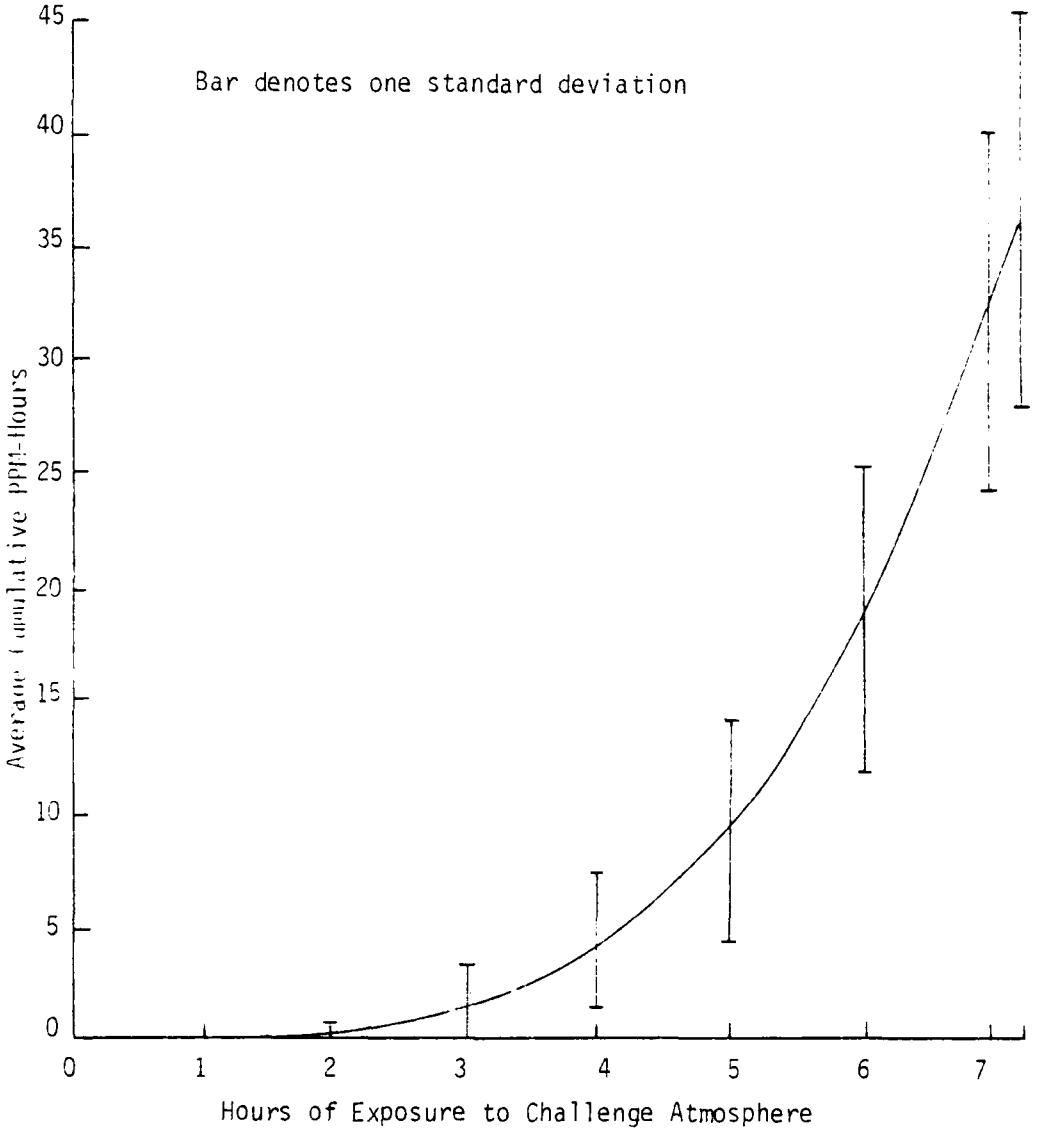


Figure 14--Average cumulative PPM-Hours inside respirators.

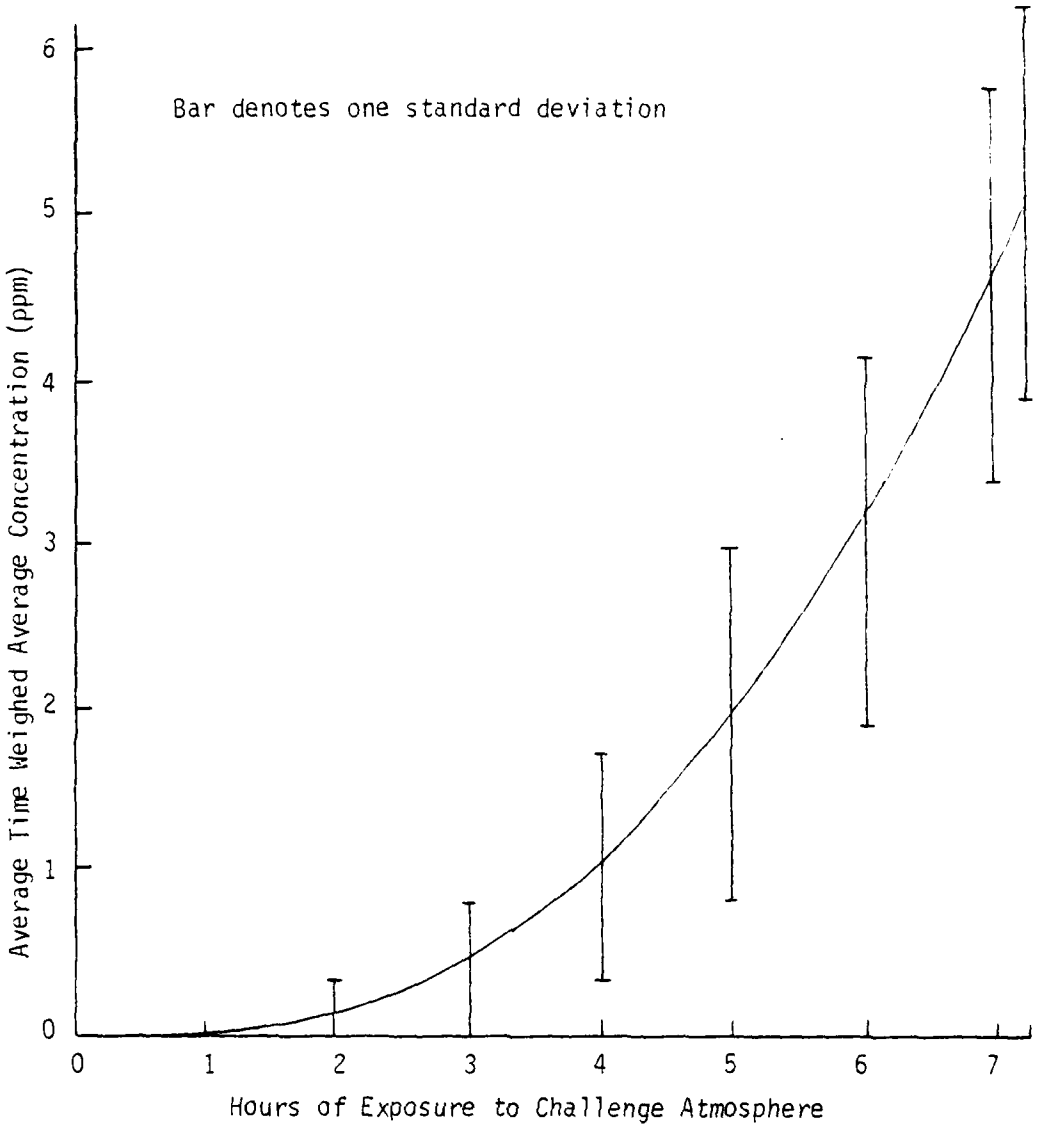


Figure 15--Average of Time Weighed Average concentrations.

The computed standard deviation was 3.9 ppm. The bound on the error of estimation was computed as 3.51 ppm.

A t-test was performed to determine if the population mean peak Halothane concentration inside of the respirator after 7.25 hours of exposure was less than 50 ppm. The test indicated that the population mean peak Halothane concentration inside of the respirator was less than 50 ppm ($p < 0.005$).

After 7.25 hours of exposure to the challenge halothane atmosphere, the time weighed average (TWA) concentration of Halothane that had been inside of the respirator ranged from 3.56 to 6.36 ppm. The sample mean was 5.04 ppm. The computed standard deviation was 1.21 ppm and the bound on the error of estimation was 1.18 ppm.

A t-test was performed to determine if the population mean TWA concentration inside of the respirator after 7.25 hours of exposure was less than 50 ppm. The test indicated that the population TWA concentration inside of the respirator after 7.25 hours of exposure was less than 50 ppm ($p < 0.005$).

# DISCUSSION

The experimental results of this research found that the peak and time weighed average concentration inside of the 3M#8711 respirator after 7.25 hours of exposure to the challenge Halothane concentration was less than 50 ppm, the Threshold Limit Value. Since these experiments were conducted with no water in the test chamber other than that water vapor in the ambient air, they cannot be considered as representative of the results when a human wears the respirator.

The experimental plan was to also humidify the exhalation breath to approximately 100% relative humidity by placing water in the bellows. Unfortunately, due to equipment failure, water could not be contained in the bellows and data could not be obtained. However, it should be noted that the five experiments performed for this thesis were accomplished only after many other respirators had been tested under a variety of conditions, with and without water in the bellows. The results of these preliminary studies, described in Appendix D, provided considerable insight as to how the 3M #8711 respirator would perform when worn by a human.

Most importantly, the preliminary studies revealed that the evaluation of valveless respirators is more complex than the evaluation of respirators with an exhalation valve. Respirators with an exhalation valve are not partially cleansed by an exhalation breath because the exhalation breath does not pass through the sorbent bed when exiting

the respirator. On the other hand, valveless respirators such as the 3M #8711 are partially cleansed by each exhalation breath. The preliminary studies indicated that the amount of cleansing action depends upon the amount of material in the breathing system that can absorb Halothane.

When a breathing system has no absorptive material, any Halothane vapor which penetrates the mask is available to become part of the exhalation breath. The breath is "dirty". However, when a mechanical or human breathing system has absorptive material available, Halothane vapor which penetrates the respirator can be partially absorbed. Consequently, there is less Halothane vapor available to become part of the exhalation breath. The preliminary studies indicate that this "cleaner" exhalation breath is more efficient in regenerating the activated charcoal in the respirator than the "dirtier" exhalation breath of a system with no absorptive material. The Bendix study helps to confirm this hypothesis.

An analysis of the Bendix experimental method reveals that their equipment generated a "totally clean" exhalation breath. In effect, their equipment simulated a breathing system which contained a considerable amount of absorptive material that could completely clean each exhalation breath. Using this "totally clean" exhalation breath, Bendix concluded that the contaminant concentration inside of the mask would be kept at a level of less than 10% of the challenge concentration. In other words, the "clean" exhalation breath was extremely

efficient in regenerating the activated charcoal in the respirator.

To determine if the interpretation of the Bendix data was correct, several preliminary studies used an activated charcoal cannister in the breathing system to totally cleanse the exhalation breath. The experimental results confirmed the Bendix study and indicated that the concentration inside of the mask would be at a level of less than 10% of the challenge concentration when there was a considerable amount of absorptive material in the breathing system.

When the results of the preliminary and Bendix studies are analyzed, it appears that the respiratory protection provided by the valveless respirator improves as the amount of absorptive material in the breathing system increases. The amount of absorptive material needed in the breathing machine to simulate a human system is not known. However, it appears that the preliminary studies conducted with no water in the system and the Bendix studies establish breakthrough curves which form boundries for additional research. The preliminary work performed with no water or charcoal filter in the system had no absorptive material and produces breakthrough curves which rise too quickly. The Bendix experimental method has essentially infinite absorptive material and the resultant breakthrough curves rise too slowly. The preliminary work performed with water in the system had some absorptive material in the system and is felt to simulate the human response. Consequently, it would appear that the human response produces breakthrough curves which fall within the two extreme breakthrough curves as shown on

Figure 26 (p. 80).

The thesis work was performed with no absorptive material in the breathing system. If the preliminary studies are true, an experiment conducted with no absorptive material in the system makes the respirator perform poorly - i.e., the contaminant breaks through the respirator quicker that if absorptive material were present in the breathing system. Consequently, if a respirator provides suitable respiratory protection when it is evaluated with no absorptive material in the breathing system, one can infer that the same respirator would provide better protection when worn by a human.

# CONCLUSIONS

The conclusions to be derived from this research are the following:

1. Reject Null Hypothesis I. Conclude that at the 99.5% confidence level, the population mean peak Halothane concentration inside of a 3M #8711 respirator will be less than 50 ppm when there is no water in the breathing system and the respirator has been exposed to a challenge atmosphere of approximately 140 ppm for 7.25 hours.
2. Reject Null Hypothesis II. Conclude that at the 99.5% confidence level, the population mean time weighed average Halothane concentration inside of a 3M #8711 respirator will be less than 50 ppm when there is no water in the breathing system and the respirator has been exposed to a challenge atmosphere of approximately 140 ppm for 7.25 hours.
3. The related respirator study data provided in Appendix D and the thesis data permit the development of inferences pertaining to the use of the 3M #8711 respirator by humans in the hospital operating suite.

# RECOMMENDATIONS

The experiments performed for this thesis raised many questions that were not answered. Suggested future work in this area includes:

1. Using a Halothane challenge atmosphere of 3000 ppm, replicate the breakthrough experiments with no water in the bellows a sufficient number of times to make the results statistically valid. Using the same challenge atmosphere, replicate breakthrough experiments with one liter of water in the bellows to statistically validate the breakthrough curves. Analyze the data to determine if experiments with no water in the bellows are significantly different from experiments with one liter of water in the bellows.

2. Using a Halothane challenge atmosphere of 3000 ppm, replicate the breakthrough experiments with 0.5, 1, and 2 liters of water in the bellows to statistically validate the results. Analyze the data to determine if the breakthrough curves level out at a value less than 100% breakthrough. Also analyze the level section of the curves to see if the amount of water in the bellows makes the curves statistically different.

3. Investigate the physiological uptake of Halothane in the body to determine how much water must be in the bellows to simulate the human absorption effect.

4. Investigate the equilibrium phenomina which appears to cause the percent breakthrough to level out when there is water in the bellows.

Determine if the percent breakthrough will remain constant after the water is saturated with Halothane or will the percent breakthrough eventually reach 100% breakthrough after the water is saturated.

5. Using respirators that have experienced a given percent breakthrough, remove the challenge atmosphere to simulate that the person is in an area free of Halothane. Investigate the decay of Halothane inside of the respirator.

6. Determine the experimental method (contaminant, equipment, and absorbant) to be used as a part of a certification program for valveless respirators.

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# APPENDIX A

## Open Loop Halothane Generator System

# APPENDIX A

## OPEN LOOP HALOTHANE GENERATOR SYSTEM

A closed loop Halothane generation system was used for the research to keep the Halothane challenge atmosphere concentration constant. However, initially, an open loop system was used. Although this open loop system was eventually rejected for this research, the concept has potential application in other cases and is discussed in this appendix to assist future researchers.

A schematic diagram of the open loop Halothane generation system is shown in Figure 16. The compressed air line of the laboratory is used as the driving force to inject Halothane vapor into the test chamber. The compressed air line is connected to an 18 inch high stainless steel cylinder that is approximately four inches in diameter. A glass tube, called Corning Vycor glass, number 7930, is inserted in one end of the cylinder. The Vycor glass is porous and a liquid placed inside the glass tube leaches to the outside surface of the glass. Consequently, a thin film of the liquid forms on the exterior surface of the glass. The liquid inside the glass acts as a reservoir to replenish that liquid which leaches to the surface and evaporates.

The stainless steel cylinder acts as a mixing chamber. Liquid Halothane is placed in the glass tube. The Halothane leaches to the surface of the glass where the air flow evaporates it and injects the vapor into the respirator test chamber. The amount of Halothane

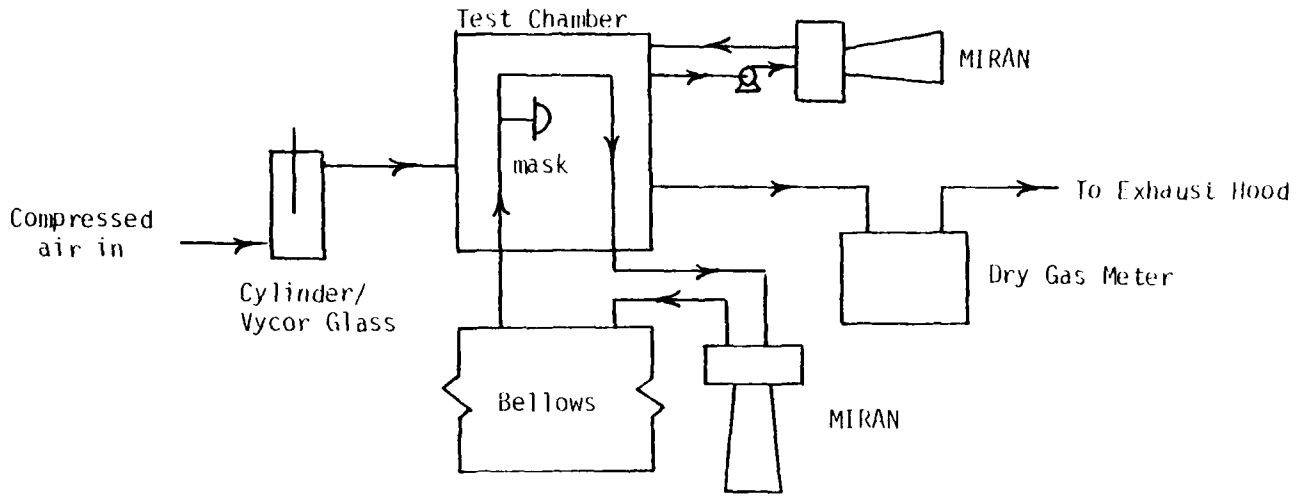


Figure 16--Test chamber with open loop halothane generation system.

vapor permitted to be injected is governed by the length of Vycor glass tubing inside the stainless steel cylinder. If a higher concentration of Halothane is required, the O-ring and screw which restrains the Vycor tubing is released and the tubing shoved deeper into the cylinder. See Figure 17 for a schematic of the cylinder/Vycor glass system. With more of the tubing in the cylinder, there is more glass surface area in the cylinder. It follows that there is more Halothane evaporating in the cylinder and the concentration in the test chamber rises. The MIRAN monitoring the challenge atmosphere indicates when the glass is sufficiently deep enough into the cylinder. The tubing is similar to a slide trombone.

This open loop generation system used a great deal of liquid Halothane. Since the challenge atmosphere was continually exhausted to a laboratory hood, the liquid level in the Vycor glass was quickly depleted. Consequently, the system required a great deal of attention and it could not be operated overnight without someone monitoring the liquid Halothane level in the glass. Therefore, the open loop system was discarded and the closed loop system was used instead. However, the cylinder/Vycor glass system is good to generate very low concentrations of a contaminant and may be of some value to the reader during a different type of research.

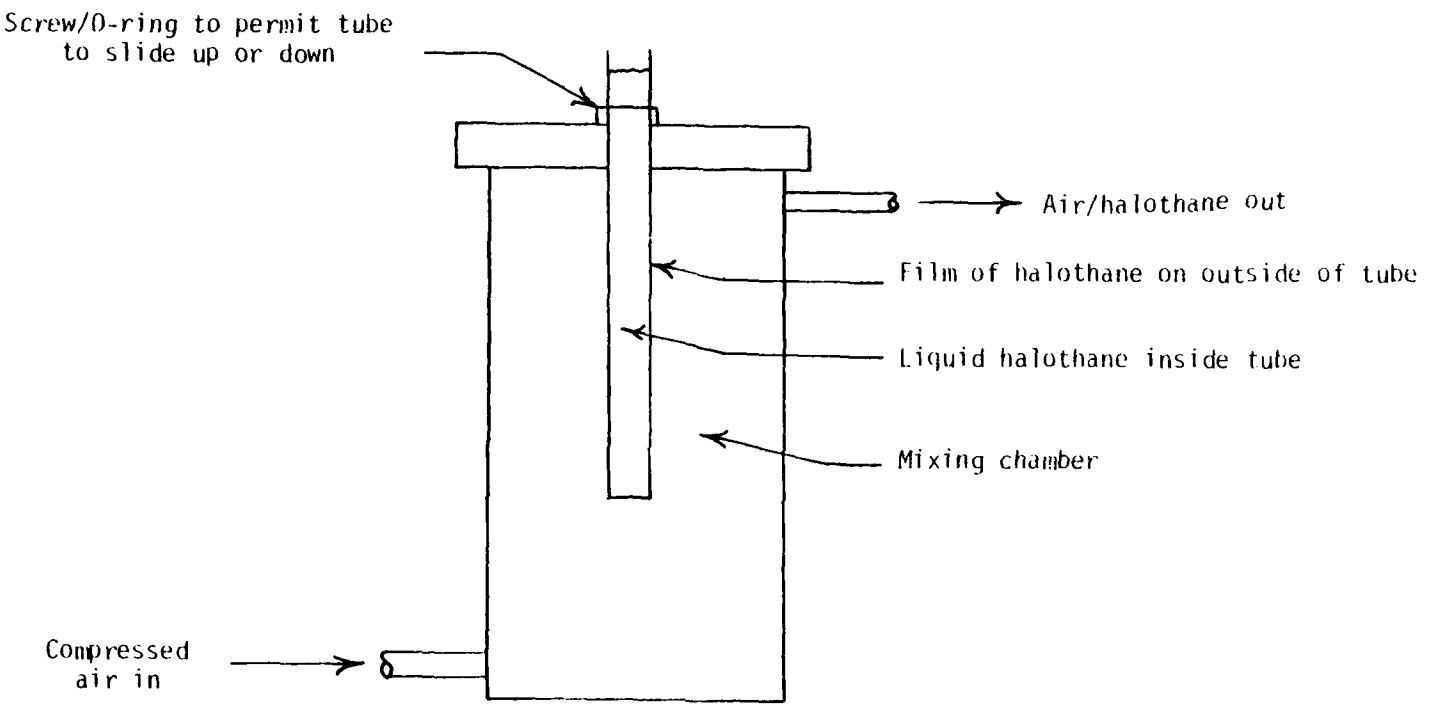


Figure 17--Detail of mixing cylinder/Vycor glass.

# APPENDIX B

## Calibration of MIRAN Infrared Monitors

# APPENDIX B

## CALIBRATION OF MIRAN INFRARED MONITORS

The MIRAN instruments were calibrated using the closed loop calibration set-up shown in Figure 7 (p. 20). Various microliter amounts of liquid Halothane were injected into the system and the absorbance readings on the MIRAN instrument recorded. Calibration curves were established at three pathlengths to provide absorbances for the range of Halothane concentrations expected during the research.

The following equation was used:

$$C = \frac{d \cdot V(\text{liquid}) \cdot MV \cdot 10^6}{MW \cdot V \cdot 1000}$$

where $d$ = liquid density of Halothane = 1.87 $gm/cm^3$

$V(\text{liquid})$ = Volume (uL) of liquid Halothane injected into the closed loop system

$MV$ = Molar volume = 24.94 L/gm mole at $25^oC$/745 mm Hg

$MW$ = Molecular weight of Halothane = 197.4 gm/gm mole

$V$ = Volume (L) of MIRAN closed loop system = 5.64 L

$C$ = parts per million (ppm) concentration of Halothane in the MIRAN closed loop system

1000 = Conversion factor = 1000 $uL/cm^3$

$10^6$ = Conversion factor for parts per million

EXAMPLE: If 5 uL of Halothane is injected into the closed loop system, the concentration of Halothane vapor in the MIRAN would be:

$$C = \frac{(1.87)(5)(24.94)(10^6)}{(197.4)(5.64)(1000)} = 209.4 \text{ ppm Halothane}$$

The absorbance reading shown on the MIRAN for the pathlength selected would be equal to 209.4 ppm. If desired, other microliter amounts of Halothane could be injected into the system and the MIRAN absorbance readings plotted on graph paper.

Tables VIII and IX list the calibration data collected for this research.

Table VIII

Calibration Data for MIRAN Used to Monitor Challenge Atmosphere

| Pathlength (Meters)* | Halothane Injected (uL) | Concentration (ppm) | Absorbance (A) Reading on MIRAN |
|---|---|---|---|
| 0.75 | 25 | 1047 | 0.355 |
| 0.75 | 50 | 2094 | 0.635 |
| 0.75 | 73 | 3058 | 0.850 |
| 2.25 | 6.0 | 251 | 0.25 |
| 2.25 | 12.3 | 515 | 0.48 |
| 2.25 | 18.5 | 775 | 0.665 |
| 2.25 | 24.6 | 1030 | 0.81 |
| 2.25 | 29.0 | 1215 | 0.915 |
| 20.25 | 2.0 | 84 | 0.645 |
| 20.25 | 3.0 | 125 | 0.88 |
| 20.25 | 3.5 | 146 | 0.98 |

* Wavelength = 12.3 uM

Table IX

Calibration Data for MIRAN Used to Monitor
Halothane Concentration Inside of the Bellows

| Pathlength (Meters)* | Halothane Injected (uL) | Concentration (ppm) | Absorbance (A) Reading on MIRAN |
|---|---|---|---|
| 0.75 | 25 | 1047 | 0.35 |
| 0.75 | 50 | 2094 | 0.645 |
| 0.75 | 73 | 3058 | 0.86 |
| 2.25 | 6.0 | 251 | 0.27 |
| 2.25 | 12.3 | 515 | 0.48 |
| 2.25 | 18.5 | 775 | 0.68 |
| 2.25 | 24.6 | 1030 | 0.83 |
| 2.25 | 29.0 | 1215 | 0.94 |
| 20.25 | 0.3 | 12.5 | 0.12 |
| 20.25 | 3.0 | 125 | 0.89 |

* Wavelength = 12.3 uM

# APPENDIX C

## Statistical Analysis of Data

# APPENDIX C

## STATISTICAL ANALYSIS OF DATA

### Determining the Bound on the Error of Estimation

To determine the bound for the peak mean halothane concentration inside of the 3M #8711 respirator, the data from Tables II-VI (p.28-32) is used. From the Tables, the peak halothane concentration in ppm inside of the mask after 7.25 hours of exposure to the challenge atmosphere is 21, 24, 14, 16.5, and 17.5 ppm. From this data, the following is computed.

$n = 5$

$\bar{X} = 18.6$ ppm

$s^2 = 15.425$

$s = 3.92$ ppm

where $n$ = number of samples

$\bar{X}$ = mean = $\frac{\sum X_i}{n}$

$X_i$ = "i"$^{th}$ sample

$s^2$ = variance = $\frac{1}{n-1}\left[\sum X_i^2 - \frac{(\sum X_i)^2}{n}\right]$

$s$ = standard deviation = $\sqrt{s^2}$

A bound on the error of estimation (B) is calculated by using the equation:

$$B^2 = \frac{4 \cdot s^2}{n}$$

Using the data from the five experiments, the bound is:

$$B^2 = \frac{(4)\ (15.425)}{5} = 12.34$$

$$B = 3.51 \text{ ppm}$$

To determine the bound for the mean Time Weighed Average (TWA) halothane concentration inside of the 3M #8711 respirator, the data from Table VII (p. 33) are used. From the Table, the TWA Halothane concentration in ppm inside of the mask after 7.25 hours of exposure to the challenge atmosphere is 4.32; 6.22; 4.74; 3.56; and 6.36 ppm. From this data, the following is computed.

$$n = 5$$

$$\tilde{X} = 5.04 \text{ ppm}$$

$$s^2 = 1.481$$

$$s = 1.217 \text{ ppm}$$

Using the data from the five experiments, the bound is:

$$B^2 = \frac{(4)\ (1.481)}{5} = 4.89$$

$$B = 1.18 \text{ ppm}$$

T-test to Determine Population Mean Peak

Concentration Inside of the Respirator

Null Hypothesis $H_o$: $\mu_{peak} \geq 50$ ppm

Alternative Hypothesis $H_a$: $\mu_{peak} < 50$ ppm

Test Statistic: $t = \frac{\bar{X} - 50}{s/\sqrt{5}}$ is a t with 4 degrees of freedom

$$t = \frac{18.6 - 50}{3.92/\sqrt{5}} = -17.91$$

Reject Region: Reject $H_o$ if $t < -t_{n-1,\alpha} = -t_{4,0.005}$

$= -4.604$

$-17.91$ is less than $-4.604$

Conclusion: Reject $H_o$. Conclude that the population mean peak concentration inside the mask after 7.25 hours of exposure to approximately 140 ppm halothane is less than 50 ppm.

T-test to Determine Population Mean Time Weighed

Average (TWA) Concentration Inside of the Respirator

Null Hypothesis $H_o$: $\mu_{TWA} \geq 50$ ppm

Alternative Hypothesis $H_a$: $\mu_{TWA} < 50$ ppm

Test Statistic: $t = \frac{\bar{X} - 50}{s/\sqrt{5}}$ is a t with 4 degrees of freedom

$$t = \frac{5.04 - 50}{1.21/\sqrt{5}} = -83.08$$

Reject Region: Reject $H_o$ if $t < -t_{n-1,\alpha} = -t_{4,0.005}$

$= -4.604$

-83.08 is less than -4.604

Conclusion: Reject $H_o$. Conclude that the population mean TWA concentration inside the mask after 7.25 hours of exposure to approximately 140 ppm halothane is less than 50 ppm.

# APPENDIX D

## Preliminary Respirator Performance Studies

# APPENDIX D

## PRELIMINARY RESPIRATOR PERFORMANCE STUDIES

The Bendix study of valveless disposable respirators indicated that the maximum amount of contaminant which would penetrate the respirator would be approximately 10% of the challenge concentration or less. The Bendix study, however, used an experimental method which exhausted any contaminant that penetrated the respirator and used clean air as an exhalation breath. Under actual human usage, some of the contaminant which penetrates the respirator will be part of the exhalation breath. The research conducted at Brooks AFB used equipment that would not exhaust any contaminant that had penetrated the respirator. It was felt that this experimental method imitated the human respiratory system more closely than the Bendix study.

Initial experiments were conducted in a "dry" state. That is, the exhalation breath through the respirator was not humidified. Rather than leveling off at about 10% of the challenge concentration as suggested by the results of the Bendix study, the Halothane vapor continued to breakthrough the mask until there was 100% breakthrough. Figure 18 shows the breakthrough curves obtained at various Halothane challenge concentrations. The higher the challenge concentration, the faster the breakthrough. This observation infers that the valveless respirator will eventually reach 100% breakthrough just as respirators with exhalation valves.

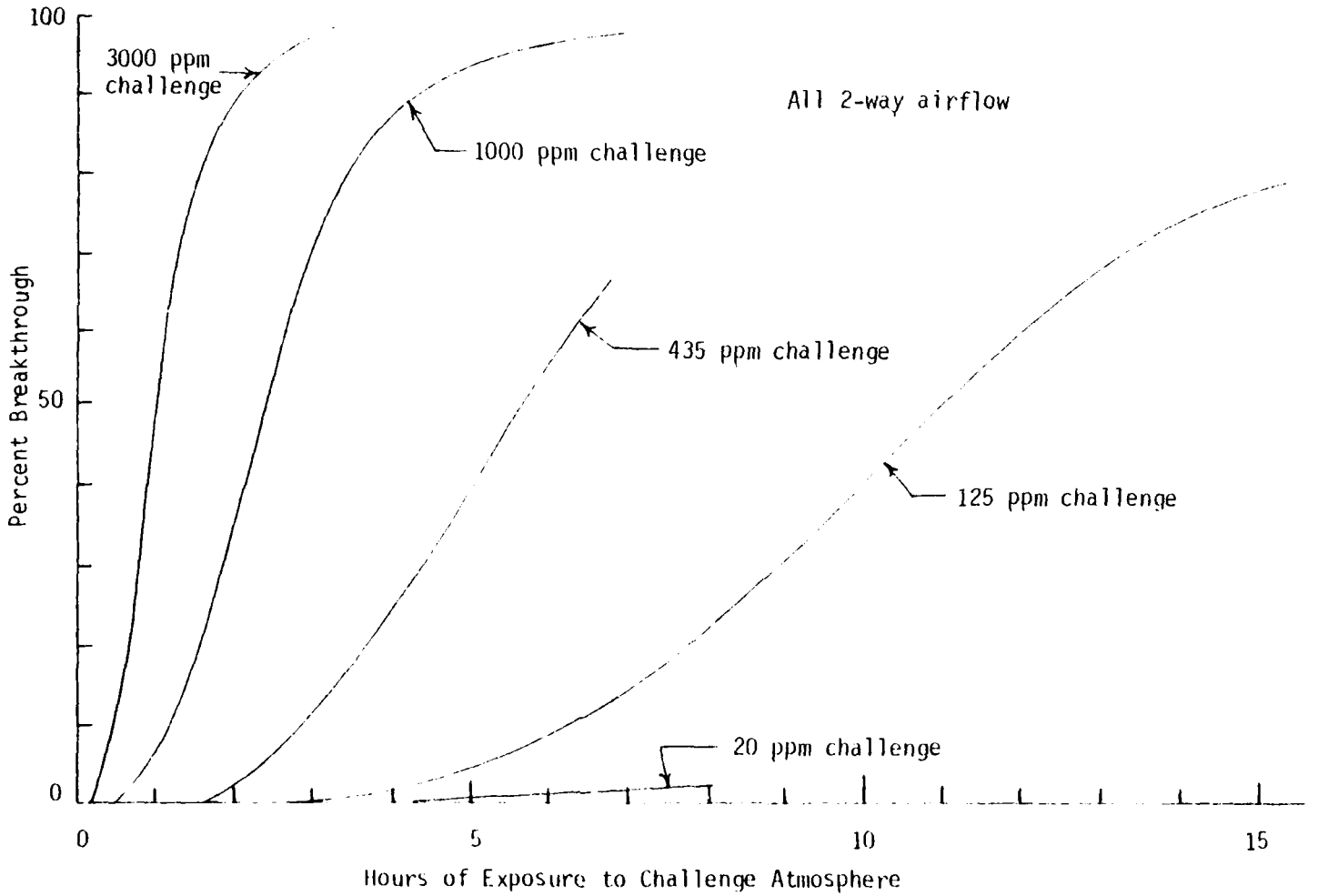


Figure 18--Percent breakthrough versus exposure time for various challenge concentrations.

The next step was to humidify the exhalation breath to see if there was a change in the breakthrough curves. One hundred milliliters of distilled water was placed in the stainless steel bellows chamber to humidify the exhalation breath. The resultant breakthrough curve appeared to level off at less than 100% breakthrough. But, after about four hours into the experiment, the water in the bellows had evaporated and the breakthrough curve began to climb towards 100% breakthrough.

Another experiment was performed which used one liter of distilled water in the bellows. This experiment proceeded for 10 hours. Figure 19 shows the relationship between the dry experiment and the two humid experiments at a challenge atmosphere of 3000 ppm Halothane. Note that with an increasing amount of water in the bellows, the percent breakthrough curve levels out lower than 100% breakthrough. In addition, note that it takes longer to attain a given percent breakthrough. It was theorized that this change in the breakthrough curves was due to the water acting as an absorber. Halothane is soluble in water and the Halothane was probably being taken into solution. The Halothane vapor taken into solution was not available to become part of the exhalation breath. Consequently, the exhalation breath was "cleaner" in that it contained less halothane vapor. It appears that the cleaner exhalation breath was able to do a better job of washing out the activated charcoal in the respirator. Since the activated charcoal was partially regenerated with each exhalation breath, the breakthrough

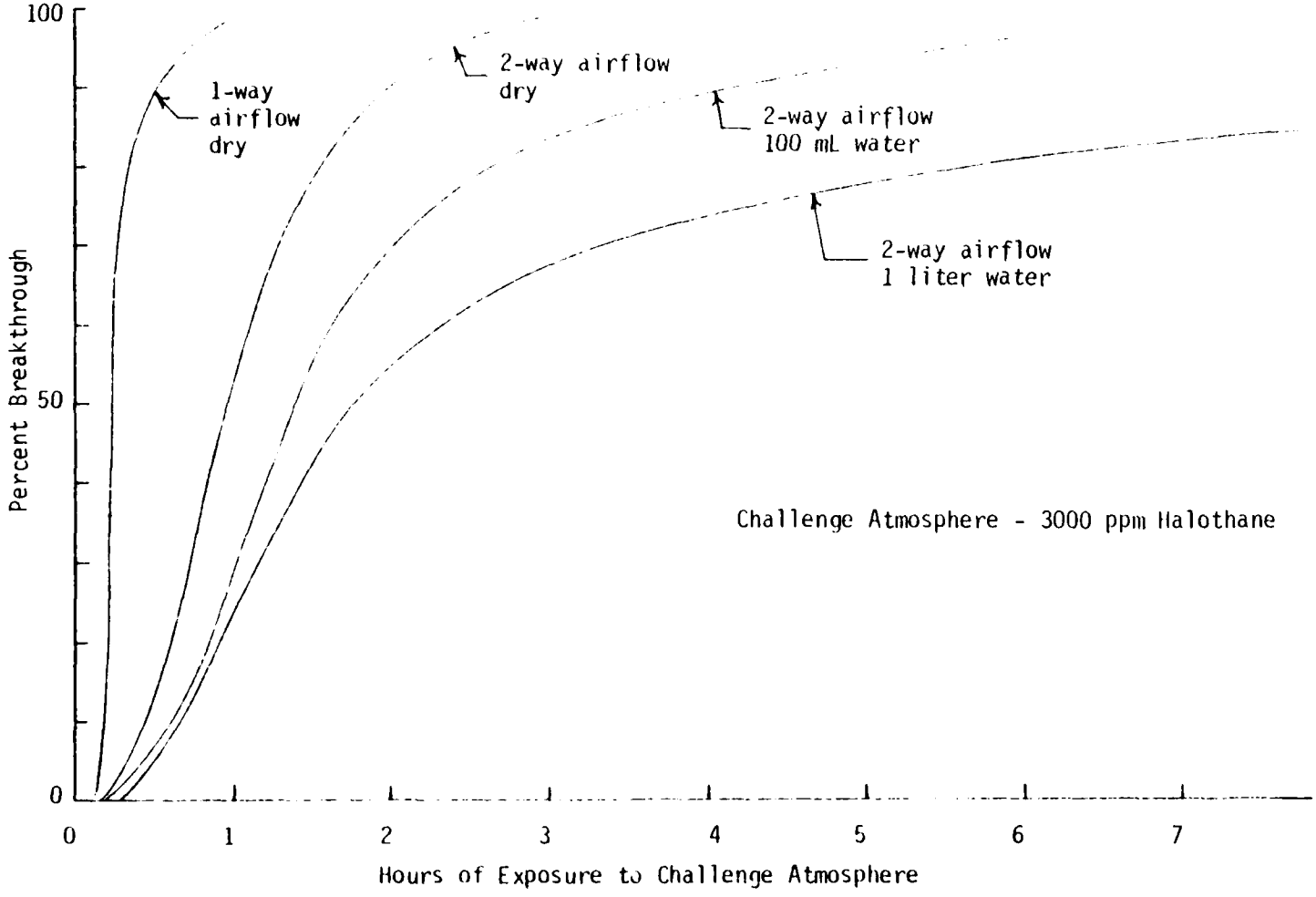


Figure 19--Variation in breakthrough curves as water is added to the bellows.

curves took longer to reach a given percent breakthrough.

Figure 20 shows a typical breakthrough curve from the Bendix study. Although the curve leveled out at a small percent breakthrough value, the curve is similar to the curves of Figure 19 when water was in the bellows. It was theorized that the Bendix experimental method, that of exhausting all contaminant that penetrated the respirator, was essentially a "total absorber" experiment. That is, none of the contaminant vapor would ever be part of the exhalation breath because it had been exhausted from the system. The preliminary studies with water in the bellows were essentially "partial absorber" experiments since some of the contaminant vapor was removed from the system by the water. Finally, the preliminary studies with no water in the system were "zero absorber" experiments as all of the contaminant vapor that had penetrated the respirator was available to be part of the exhalation breath.

In an attempt to duplicate the Bendix experiments, a charcoal filter was placed at the exit of the MIRAN. Figure 21 shows the placement of the filter. No water was in the bellows. Any Halothane which penetrated the respirator was pumped to the MIRAN for monitoring and then was filtered out of the system by the charcoal filter. The experiment was conducted at a challenge of 1000 ppm Halothane. The breakthrough curve can be seen as Figure 22. Note that the curve levels out at less than 10% breakthrough. This experiment confirms the Bendix study and suggests that if the human body had an infinite

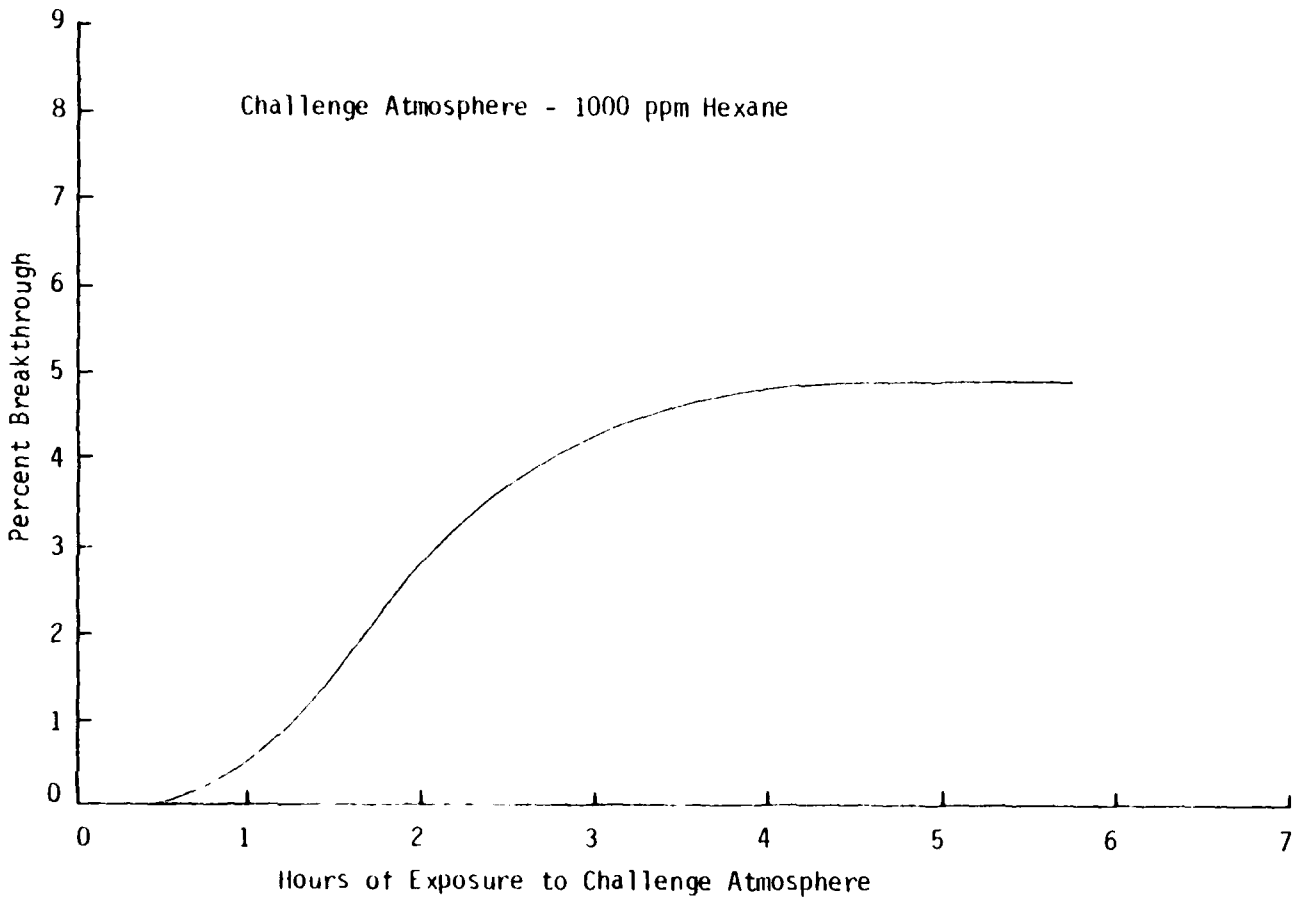


Figure 20--Typical breakthrough curve of Bendix study.

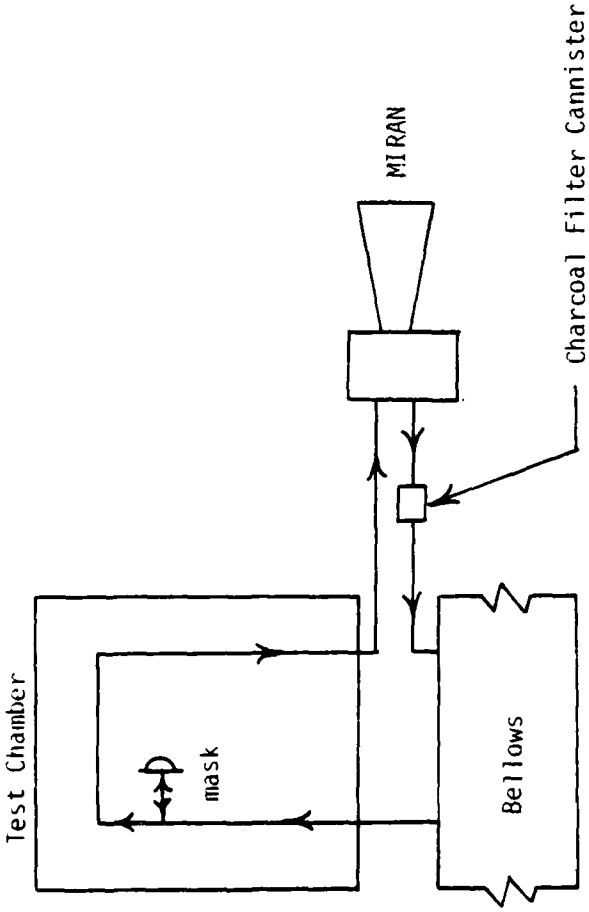


Figure 21--Diagram showing location of activated charcoal filter used to simulate Bendix study.

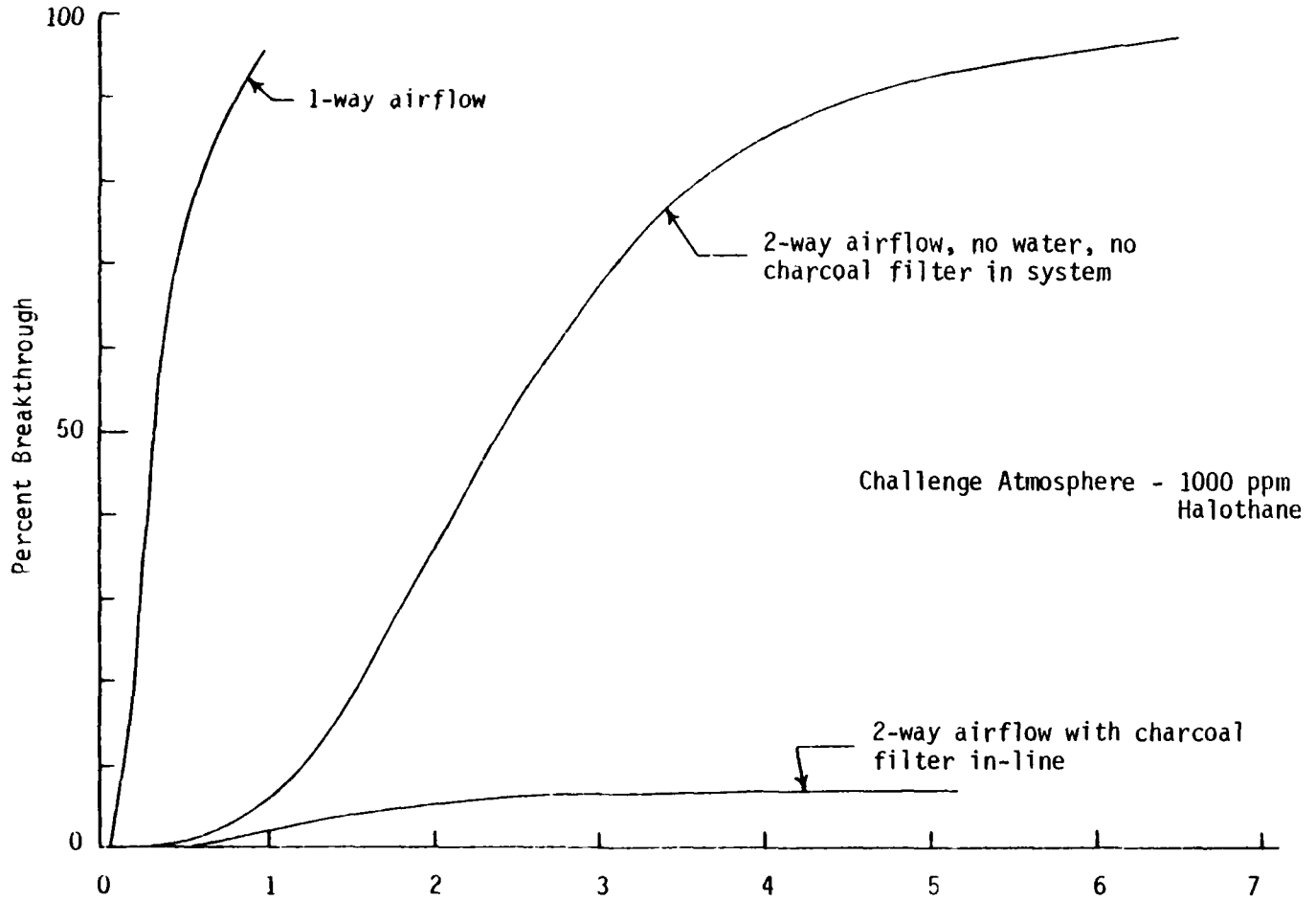


Figure 22--Breakthrough curves for 1-way airflow, 2-way airflow, and 2-way airflow with charcoal filter in system.

capacity to absorb the Halothane that penetrates the respirator, the maximum concentration inside the mask would probably be as reported by Bendix, i.e., 10% or less of the challenge concentration. On the other hand, the experiments performed with no water or charcoal filter in the bellows suggest that if the body had no capacity to absorb the Halothane that penetrates the respirator, the concentration inside of the mask would essentially reach the level of the challenge concentration, i.e., would reach 100% breakthrough. The speed with which 100% breakthrough occurred depended upon the concentration of the challenge atmosphere. Thus, it would appear that an upper and lower bound can be set 1) by testing the respirator with no water and no charcoal filter in the system, and 2) by testing the respirator with no water in the system, but with a charcoal filter in the system.

Noting that the human body is largely composed of water, it is theorized that the actual breakthrough curve for a human using the valveless respirator is somewhere between the extremes discussed.

The 3M Company is also selling a disposable organic vapor respirator that has an exhalation valve - the 3M #8709 respirator. The 3M #8709 respirator is essentially a 3M #8711 respirator fitted with an exhalation valve. With an exhalation valve, the air flows through the sorbent bed in one direction. As previously discussed, the air flows through the 3M #8711 sorbent bed in two directions.

To understand how this exhalation valve would affect the respirators performance, the test equipment at Brooks AFB was modified

so that the airflow through the 3M #8711 respirator would be in one direction, thus simulating the 3M #8709 respirator. Figure 23 and Figure 24 show how the one-way valve system in the "throat" area was modified to achieve one-way flow through the respirator. Figure 25 shows the percent breakthrough curves for one-way airflow through the 3M #8711 respirator. By comparing Figure 18 (p. 69) to Figure 25, it is seen that for a given challenge atmosphere concentration, one-way airflow would result in 100% breakthrough much faster than the two-way airflow of the 3M #8711.

To summarize, the data collected in the experiments discussed in this appendix suggest that for a given Halothane challenge concentration, typical breakthrough curves would be as shown in Figure 26. The graph indicates that when a water absorber is present, the protection afforded by the respirator improves. It is theorized that the efficiency of the respirator improves as the amount of Halothane in the exhalation breath decreases. With a Halothane absorber such as water or a charcoal filter in the breathing system, the exhalation breath is "cleaner". The clean breath does a better job of flushing the Halothane bound to the activated charcoal impregnated in the respirator. Consequently, it takes longer for a given percent breakthrough to occur.

The graph of Figure 26 implies that the respirator tests conducted with no water in the system will result in contaminant breakthrough at a much quicker rate than if water or a charcoal filter had been in the

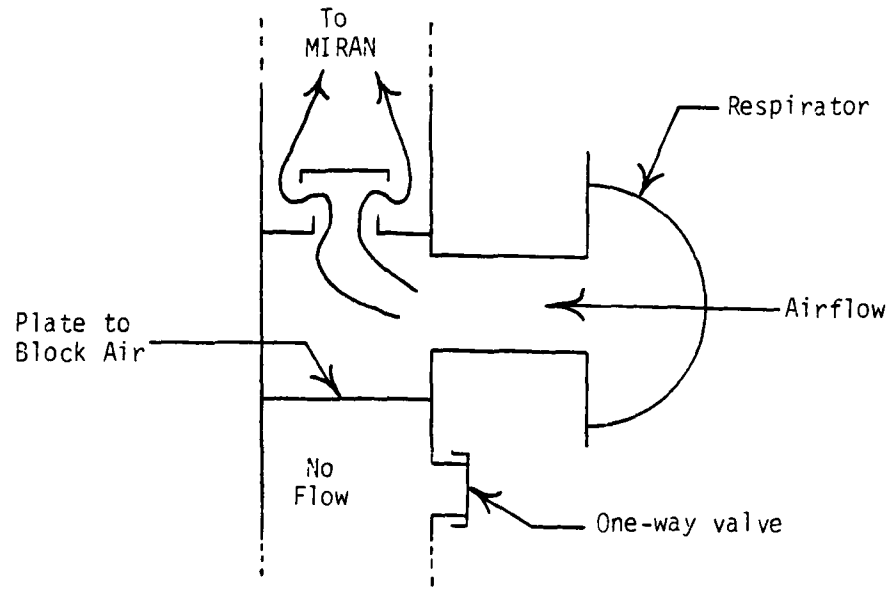


Figure 23--One-way airflow through respirator (inspiration).

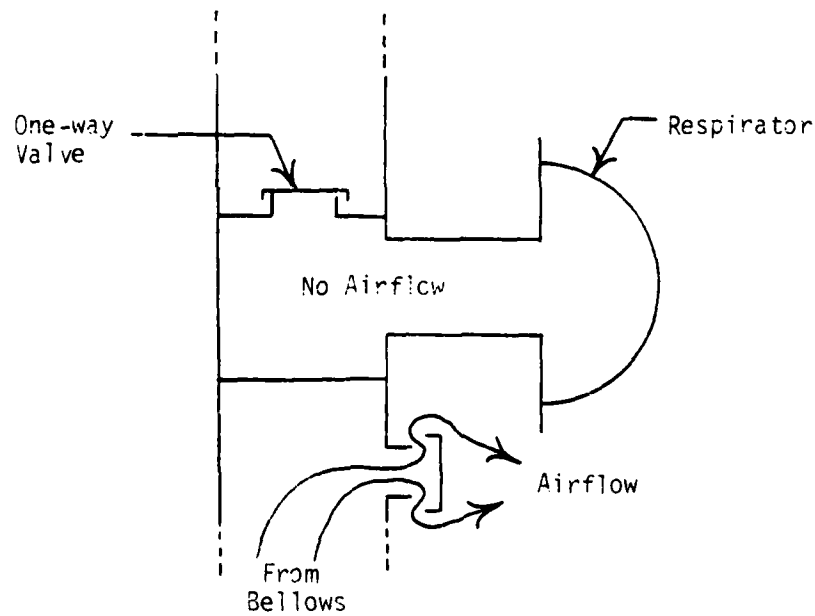


Figure 24--One-way airflow through respirator (expiration).

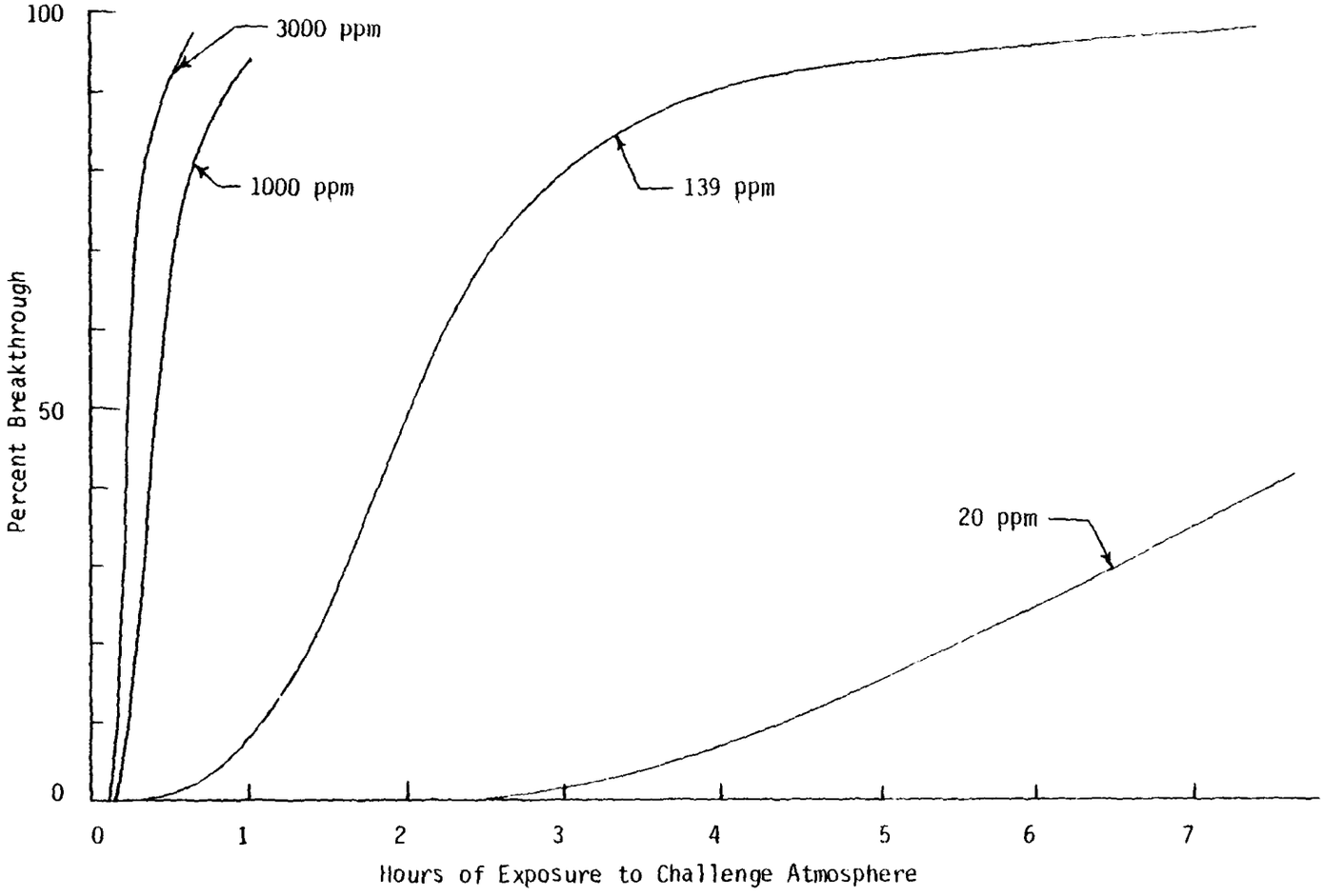


Figure 25--Percent breakthrouhh curves for 1-way airflow, various challenge concentrations.

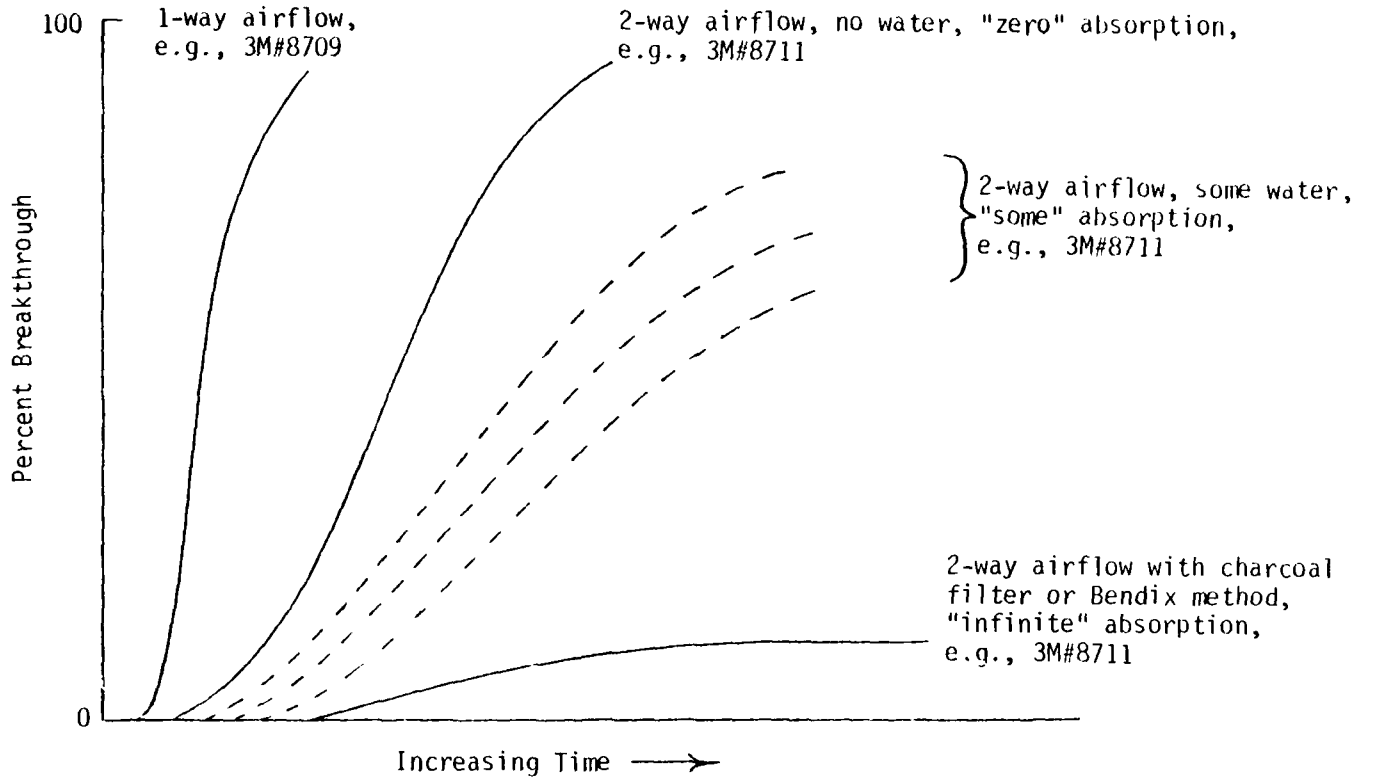


Figure 26--Expected typical breakthrough curves

for a given challenge concentration.

system. Consequently, the data suggests that the valveless respirator would provide better protection when worn by a human because of the liquids in the body.

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# APPENDIX E

## Apparatus Used For The Research

# APPENDIX E

## APPARATUS USED FOR THE RESEARCH

1. Wilks MIRAN I Variable Filter Infrared Analyzers, Serial Numbers 410, 63-300.

2. Masterflex Pump, Serial Number 116A78869, Model 7017-2, Cole Parmer, Chicago, Illinois.

3. Water Chiller, Forma Scientific, Serial Number 5311-95, Model 2095, Marietta, Ohio.

4. Constant Flow Sampler Pumps, E.I. DePont De Nemours, Model P-200, Serial Number 9005; Model P-30, Serial Number 9913.

5. Hygrometer, Panametrics, Model 2000, Serial Number 437, Waltham, Mass.

6. Proportional Temperature Controllers, Yellow Springs Instrument Company, Model 72, Serial Numbers 201, 778, and 779.

7. Heating Blankets, Electro-flex Heat, Model 107-117, Bloomfield, Conn.

8. Function Generator, 40 MHz Tektronic TM503, Serial Number B121184.

9. Bellows, Metal Bellows Corp., Model MB-21, Serial Number 6414.

10. Bellows Motor, Slo-Syn Motor, Superior Electric Company, Type HS1500, Bristol, Conn.

11. Strip Chart, Linear Instrument Corp, Model 252a, Irvine, Calif.

12. Absolute Pressure Gauge, Wallace & Tiernan, Model FA129, Serial Number 06502, Billville, NJ.

13. Respirometer, Warren E. Collins Co., Serial number 1665, Boston, Mass.

14 Halothane U.S.P. Liquid, Halocarbon Laboratories, Inc., Hackensock, NJ.

# VITA

Glenn L. Gaudet was born October 19, 1946 in Providence, Rhode Island to Elton H. and Walburga R. Gaudet. His parents were originally from Louisiana and, in 1947, returned to New Orleans to reside. After graduating from Holy Cross High School in New Orleans in 1964, he attended Tulane University of Louisiana. He received his Bachelor of Science degree in Chemical Engineering in May 1968. In June 1968, he entered the United States Air Force as a Second Lieutenant and served as Bioenvironmental Engineer at Travis AFB, California from 1968 to 1972. In June 1972, he separated from the Air Force and was employed as a GS-11 Civil Service industrial hygienist at the Charleston Naval Shipyards in Charleston, South Carolina. In September 1973, he returned to active duty with the Air Force and has since served as Bioenvironmental Engineer at Richards-Gebaur AFB, Missouri; U-Tapao Royal Thai Air Base, Thailand; and Torrejon Air Base, Spain. He is currently an Air Force Institute of Technology student at Texas A&M University. He is married to the former Esther M. Torres and has one daughter, Paullette.

His permanent mailing address is:

c/o Elton H. Gaudet
4790 Hickerson Drive
New Orleans, LA 70127